IN THE SUPREME COURT OF MISSISSIPPI

Case No. 2019-M-00033-SCT

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.;
VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and
VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

Petitioners-Defendants,

vs.

JIM HOOD, STATE OF THE STATE OF MISSISSIPPI
ex rel. STATE OF MISSISSIPPI

Respondent-Plaintiff

On Petition for Interlocutory Appeal
from the Chancery Court for the First Division of Hinds County
Civil Action No. 25CH1:14-cv-001207

APPENDIX TO PETITION OF JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and VALEANT PHARMACEUTICALS NORTH AMERICA LLC FOR INTERLOCUTORY APPEAL BY PERMISSION

Volume 1 of 2

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IN THE SUPREME COURT OF MISSISSIPPI

Case No. 2019-M-00033-SCT

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VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and
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Petitioners-Defendants,

vs.

JIM HOOD, STATE OF THE STATE OF MISSISSIPPI
ex rel. STATE OF MISSISSIPPI

Respondent-Plaintiff

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from the Chancery Court for the First Division of Hinds County
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[1] The Exhibits of Petitioners included in this Appendix are consecutively numbered at the bottom of each page of this Appendix beginning with APPENDIX.0001, with an unnumbered page appearing between each Exhibit that identifies the Exhibit by letter and title.

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O	4/1/2014	U.S. Food & Drug Administration Letter Rejecting Citizens' Petitions from Cancer Prevention Coalition (Docket Nos. 94P-03420 and FDA-2008-P-0309-0001/CP)	0548
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V	9/13/2018	State's Surrebuttal in Support of Second Supplement to Memorandum of Law in Opposition to Petitioners' Motion for Summary Judgment	0786
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CERTIFICATE OF SERVICE

I hereby certify that on this day, copies of this Appendix were served on the following:

By U.S. Mail

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Hinds County Chancery Court, First Judicial District
P.O. Box 686
Jackson, Mississippi, 39201

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THIS the 8th day of January, 2019.

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Counsel for Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc.

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J. Carter Thompson, Jr. MSB No. 8195

Counsel for Valeant Pharmaceuticals International, Inc. and Valeant Pharmaceuticals North America LLC

Exhibit A

Order Denying Petitioners' Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT
OF HINDS COUNTY, MISSISSIPPI

STATE OF MISSISSIPPI, ex rel.
JIM HOOD, ATTORNEY GENERAL

PLAINTIFF

V.

CAUSE NO. G-2014-1207

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

DEFENDANTS

ORDER OF THE COURT

BEFORE THIS COURT is the *Motion for Summary Judgment* and *Joint Motion for Summary Judgment* filed herein by Defendants, Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc. (collectively "J&J") and Valeant Pharmaceutical International, Inc., and Valeant Pharmaceuticals North America, LLC (collectively "Valeant"), respectively. J&J Defendants have also filed a related *Motion to Strike Plaintiff's Second Supplement to Memorandum of Law in Opposition to Motion for Summary Judgment.* This Court has held hearing on the matter and has received proposed supporting memorandum and argument from all parties. This Court has considered all arguments as well as all relevant case and statutory law. After careful consideration, this Court hereby finds and orders as follows, to-wit:

Jim Hood, Attorney General *ex. rel.* State of Mississippi has filed this suit on behalf of the State of Mississippi itself and in a *parens patriae* capacity on behalf of the individual citizens of the State of Mississippi under the Mississippi Consumer Protection Act ("MCPA"). The Complaint was filed on August 22, 2014, in Hinds County. Plaintiff alleges that the Defendants Johnson & Johnson; Johnson & Johnson Consumer Companies, Inc. (hereinafter collectively "Johnson Defendants"); Valeant Pharmaceuticals International, Inc ("VPII") and Valeant Pharmaceuticals North America, LLC ("VPNA") misrepresented the uses, benefits, qualities and standards of the talc containing products sold by them in the State of Mississippi. Plaintiff asserts that Defendants failed to inform Mississippi residents of existing scientific evidence identifying an increased risk of ovarian cancer with the perineal use of the talc containing products. Plaintiff seeks redress from the Defendants as a result of the Defendants allegedly unlawful, unfair and deceptive business practices related to the manufacturing, sale and marketing of their talc containing products, namely, Johnson's Baby Powder ® and Shower to Shower ®, which the State claims violates §75-24-5.

Defendants herein assert that summary judgment is proper for two (2) reasons: (1) the MCPA does not apply to the labeling of cosmetic products; and (2) the State's labeling claim is preempted by the FDA's decision to reject cancer warnings for talc cosmetic products. The standard for summary judgment is well established: " The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Mississippi Rules of Civil Procedure 56(c). "All that is

required of a non-movant to survive a motion for summary judgment is to establish a genuine issue of material fact by means available under the rule." *Lyle v. Mladinich*, 584 So.2d 397, 398 (Miss. 1991).

After considering all oral and written submissions, this Court finds that there are genuine issues of material fact in this cause that may result in "triable issues." *See Great Southern Nat'l Bank v. Minter*, 590 So. 2d 129, 135 (Miss. 1991). In this case, there are clearly material issues to which one party swears to one version and the other party swears to the opposite. *See Wright v. Allstate Indemnity Co.*, 618 So. 2d 1296 (Miss. 1993). Specifically, Plaintiff alleges that Defendants knew or had reason to know by 1974 that talc products sold to women for perineal use were unsafe and likely increased the risk of ovarian cancer. Defendants dispute the same. Likewise, Plaintiff asserts that Defendants were aware of the risks associated with perineal talc product use and failed to truthfully and accurately disclose such risks . Plaintiff's assertions of failure to warn will involve a careful review of statutory schemes **in light of facts** upon which the parties simply disagree. It is not the role of this Court to try issues on a summary judgment motion, but only to decide if there are issues to be tried. *Mississippi Ins. Guaranty Association v. Byars*, 614 So. 2d 959 (Miss. 1993). In the case at hand, this Court finds that there are issues to be fully tried. Our Mississippi Supreme Court has stated that the trial court may and should deny summary judgment "when it has **any** doubt as to the wisdom of terminating the action prior to a full trial." *Donald v. Reeves Transport Co.*, 538 So. 2d 1191, 1196 (Miss. 1989) (quoting *Wright & Miller*, § 2728). In the instance of a complex legal matter involving such serious allegations, the Court

does have grave doubts as to the wisdom of terminating this action prior to a full trial. Discovery is ongoing in this matter and expert discovery has not yet commenced. The Court would be remiss in disposing of this action without allowing full development of all potentially relevant facts.

Similarly, this Court, in viewing the facts and inferences in the light most favorable to the Plaintiff, cannot **unequivocally** find that Defendants are entitled to prevail as a matter of law. Mississippi law is clear that Summary Judgment should be granted cautiously. *Brown v. Credit Center, Inc.*, 444 So. 2d 358 (Miss. 1987). In fact, our Mississippi Supreme Court has stated that all summary judgment motions should be viewed with great skepticism and that the trial court should err on the side of denying the motion. *Daniels v. GNB, Inc.*, 629 So. 2d 595 (Miss. 1993). After cautiously considering the motion in this cause, this Court simply cannot find that the strict standard for Summary Judgment has not been met. Therefore, Defendants' *Motion for Summary Judgment* pursuant to Rule 56 of the Mississippi Rules of Civil Procedure is denied. Furthermore, the Court finds that the Defendants' *Motion to Strike* is hereby rendered moot and is denied.

SO ORDERED, ADJUDGED, AND DECREED THIS the 18TH day of December, 2018.

CHANCELLOR J. DEWAYNE THOMAS

Exhibit B

Complaint

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI,
Ex rel. JIM HOOD, ATTORNEY GENERAL,

PLAINTFF

v.

JOHNSON & JOHNSON;
JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS NORTH AMERICA, LLC;

DEFENDANTS.

Civil Action No.: G2014-1207/3

FILED
AUG 22 2014
EDDIE JEAN CARR, CHANCERY CLERK
BY K. Howard D.C.

COMPLAINT

COMES NOW, the Honorable Jim Hood, Attorney General for the State of Mississippi, on behalf of the State of Mississippi, by and through the undersigned counsel (hereinafter the "State" or "Mississippi"), and files this suit in *parens patriae* against Defendants Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Valeant Pharmaceuticals International, Inc., and Valeant Pharmaceuticals North America, LLC., and in support thereof, would show unto the Court the following:

I. INTRODUCTION

1. This action is brought in the public interest for and on behalf of the People of the State of Mississippi, by the Honorable Jim Hood, Mississippi Attorney General, pursuant to the Mississippi Regulation of Business for Consumer Protection Act, and the common-law authority of the Attorney General to represent the People of the State of Mississippi.

2. The Attorney General brings this action on the State's behalf pursuant to the positive, statutory, common and decisional law of the State, including his *parens patriae* authority which vests him with the right to bring all suits necessary for the enforcement of the laws of the State and the protection of public rights.

3. This action seeks redress from Defendants Johnson & Johnson, Johnson & Johnson Consumer Companies, Inc., Valeant Pharmaceuticals International, Inc., and Valeant Pharmaceuticals North America, LLC. (collectively "Defendants" unless specifically stated otherwise) as a result of Defendants' unlawful, unfair, and deceptive business practices related to the manufacturing, sale, and marketing of their talc-containing products, namely Johnson's Baby Power® and Shower to Shower® (hereinafter the "Talc Products") in violation of Miss. Code Ann. § 75-24-5. Defendants put the health and well-being of the residents of Mississippi at risk by failing to warn of a dangerous and potentially lethal health risk associated with the use of their Talc Products, namely that women using these products on their genital area (also known as perineal use) are at an increased risk of ovarian cancer.

4. All the funds generated by this conduct were the result of the deceptive and false labeling and marketing of the Talc Products in violation of Miss. Code Ann. § 75-24-5. The ill-gotten revenue derived from Defendants' misconduct in Mississippi should, therefore, be disgorged.

5. Defendants engaged in misrepresentations and omissions in connection with the labeling, advertisements, promotion, marketing, and sale of their Talc Products. Defendants disseminated these misrepresentations and omissions in every manner possible – including on their websites, in advertisements, by mail and e-mail, and through their labeling. Defendants intentionally disseminated these misrepresentations and omissions to consumers throughout

Mississippi, and intentionally targeted minority communities. Defendants intended that Mississippi consumers would view these misrepresentations and omissions and thereby, would be induced to buy Defendants' Talc Products.

6. Pursuant to Miss. Code Ann. § 75-24-19, the Attorney General seeks civil penalties in an amount up to but not to exceed Ten Thousand Dollars ($10,000.00) for each violation of Miss. Code Ann. § 75-24-5; an injunction against future deceptive conduct pursuant to Miss. Code Ann. § 75-24-9; and, disgorgement of ill-gotten revenue pursuant to Miss. Code Ann. § 75-24-9, Miss. Code Ann. § 75-24-11, and this Court's broad equitable powers, for violations of Miss. Code Ann. § 75-24-5.

7. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of the Talc Products may have against Defendants.

8. The Attorney General disclaims any federal remedies and does not assert any claim for relief or seek any remedy arising out of a federal statute, federal regulation or provision of federal common law.

II. PARTIES

9. Plaintiff, the State of Mississippi, brings this action by and through the Attorney General for the State of Mississippi. The State of Mississippi has quasi-sovereign interests in the health, both physical and economic, and well-being of its citizenry. The State alleges that Defendants engaged in false and deceptive practices in which Defendants failed to warn the residents of Mississippi of a significant health risk associated with the Talc Products. Defendants further specifically targeted minority communities in marketing these products. The State has a quasi-sovereign interest in ensuring that companies do not violate the State's laws, endanger the health of its citizenry, or engage in discriminatory marketing putting a specific

portion of the population at greater risk. The State further has a quasi-sovereign interest in preventing the adverse direct and indirect effects of the Defendants' violations of state law on the State's economy and the citizens' economic condition.

10. The health, safety, and welfare of Mississippi's citizens have been and continue to be seriously jeopardized by the ongoing fraudulent, unfair, deceptive, and false advertisements, assurances, acts and/or practices occurring throughout the State by the Defendants. "This is a matter of grave public concern in which the State, as representative of the public, has an interest apart from that of the individuals affected. It is not merely a remote or ethical interest, but one which is immediate and recognized by law."[1] Pursuant to the established quasi-sovereign interest in protecting its citizens' health, safety, and welfare, the State, by and through its Attorney General, brings this suit in *parens patriae*.

11. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation engaged in the business of manufacturing and selling consumer products. J&J's principal place of business is located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J actively engaged in the manufacture, promotion and sale of the Johnson's Baby Powder® and Shower to Shower® during the relevant time period. J&J continues to manufacture, sell and market Johnson's Baby Powder®.

12. Defendant Johnson & Johnson Consumer Companies, Inc. ("JJCC") is a New Jersey corporation engaged in the business of manufacturing, selling and marketing consumer products including the Talc Products, namely Johnson's Baby Powder® and Shower to Shower®, during the relevant time period. JJCC continues to manufacture, sell and market Johnson's Baby

[1] *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 605 (1982) (quoting *Pennsylvania v. West Virginia,* 262 U.S. 553, 663 (1923)).

Powder®. JJCC's principal place of business is located at 199 Grandview Road, Skillman, New Jersey 08933. J&J and JJCC are hereinafter referred to collectively as the J&J Defendants.

13. Defendant Valeant Pharmaceuticals International, Inc. ("Valeant International") is a Canadian corporation with offices, manufacturing facilities and operations worldwide, including in the United States in the State of Delaware. Defendant Valeant International is the parent corporation of Defendant Valeant Pharmaceuticals North America, LLC.

14. Defendant Valeant Pharmaceuticals North America, LLC ("Valeant Pharmaceuticals"), is a corporation and is a wholly-owned subsidiary of Defendant Valeant International. Defendant Valeant Pharmaceuticals North America LLC is headquartered in North Carolina and incorporated in Delaware. Valeant Pharmaceuticals purchased Shower to Shower® from JJCC in or about September of 2012 and continues to manufacture, promote and sell Shower to Shower® to the residents of Mississippi.

15. Defendants are directly and jointly and severally liable to the State for the penalties and recovery sought herein.

16. There exists, and at various times mentioned herein there existed, a unity of interest in ownership between and among all Defendants such that any individuality and separateness between and among them ceased. Because Defendants are the alter egos of one another and exert control over each other, adherence to the fiction of the separate existence of these Defendants as entities distinct from one another will permit an abuse of the corporate privilege, sanction fraud, and promote injustice.

17. At various times relevant to the matters alleged in this Complaint, each Defendant acted as the agent of other Defendants and acted within the course and scope of the agency, regarding the acts and omissions alleged. Together, Defendants acted in concert and/or aided

and abetted each other and conspired to engage in the common course of misconduct alleged herein for the purpose of enriching themselves at the expense of the citizens of Mississippi and the State of Mississippi.

18. Upon information and belief, Defendants generated revenue derived from Mississippi during all time periods relevant to this Complaint.

III. JURISDICTION AND VENUE

19. The conspiratorial agreements, sale of the Talc Products, and other overt and/or unlawful acts complained of herein are in violation of Mississippi law, causing substantial harmful effects within the State of Mississippi. The State has suffered and will continue to suffer immediate and irreparable harm. Therefore, under Miss. Code Ann. § 75-24-9, this Court has subject matter jurisdiction over this action.

20. Jurisdiction and venue are proper in this Court pursuant to Miss. Code Ann. §§ 11-11-3, 11-5-1, 75-24-9, and 9-5-81 and Section 159 of the Mississippi Constitution. In addition, all the claims asserted herein arise exclusively under Mississippi statutory and/or common law.

21. This Court has personal jurisdiction over each Defendant under Miss. Code Ann. § 13-3-57, because each Defendant: (1) does business in Mississippi, and/or purposefully directs or directed its actions towards Mississippi; (2) committed torts in part in Mississippi against Mississippi residents; (3) solicited and continues to solicit business, and performed and continues to perform business services, such as marketing, advertising, promoting, and distributing its products in Mississippi; and, (4) has the requisite minimum contacts with Mississippi necessary to constitutionally permit the Court to exercise jurisdiction.

IV. FACTUAL ALLEGATIONS

22. Talc is a hydrous magnesium silicate, an inorganic mineral that is mined from the earth. Talc is used to manufacture many goods, such as paper making, plastic, paint and coatings, rubber, electric cable, ceramics, and cosmetics. In its loose form, and as used in the Defendants' Talc Products identified above, talc is known as "talcum powder."

23. Imerys Talc America, Inc., f/k/a/ Luzenac America, Inc. ("Imerys") and Rio Tinto Minerals Inc. ("Rio Tinto") mined the talc at issue in this case. The Defendants manufactured the Talc Products at issue in this case. The Talc Products contain substantial amounts of talc.

24. Defendants promote and market the Talc Products as a means to maintain freshness and cleanliness, eliminate friction on the skin, and absorb moisture, while keeping skin cool and comfortable. However, numerous studies over the last several decades have revealed a significant link between the use of talcum powders with an increased risk of ovarian cancer. The studies conducted over the last 30 years confirm that women who repeatedly used talc-based powders in the genital area have an increased risk of ovarian cancer compared to those women who do not.

25. Despite the potential catastrophic health consequences, Defendants have hidden and failed to warn consumers about the dangers associated with their Talc Products. Instead, Defendants intend for women to use their Talc Products in the manner most likely to result in an increased risk of ovarian cancer. Indeed, Defendants specifically marketed the products to minority communities expected to be more likely to use the Talc Products.

26. During the relevant time period, Defendants implemented a marketing strategy that specifically targeted African-American and Hispanic women within the State of Mississippi. In an August 5, 1992 document entitled "Johnson's Baby Powder...Major Opportunities," the J&J Defendants recognized and discussed its Baby Powder® sales were in decline. In an effort to

"grow the franchise," the company implemented a strategy of targeting African-American and Hispanic women since its internal studies showed these two ethnicities used Baby Powder® at higher rates than other ethnicities of women. In the same document, J&J Defendants acknowledged that: "Negative publicity from health community on talc continues . . . cancer linkage". The racially targeted strategy implemented by J&J Defendants and the other Defendants has and continues to disproportionately affect the citizens of Mississippi since approximately forty (40%) of Mississippi's population is comprised of African-American and Hispanic individuals.

27. Meanwhile, Defendants expressly and impliedly represented to these communities and the public at large that the Talc Products were safe. As a result of Defendants' omissions regarding the safety of their Talc Products, the State's residents have used the Talc Products in a potentially lethal way without any knowledge of the danger.

A. DEFENDANTS' MARKETING IS UNFAIR AND DECEPTIVE

28. For decades, Defendants have marketed their Talc Products for cosmetic use – as daily use powders safe for human use that are intended to maintain freshness and cleanliness, eliminate friction on the skin, and to absorb unwanted excess moisture for women. Nowhere have the Defendants warned of the increased risk of ovarian cancer linked to the perineal use of the Defendants' Talc Products.

29. However, as detailed below, for over 30 years, Defendants were aware of studies demonstrating that women who use talc-based baby powder in the genital area had a significant increased risk of ovarian cancer. Defendants were also informed by their talc supplier, consultants, employees, and through industry and governmental agencies that talc is unsafe and that there is a significant link between the use of talcum powders and an increased risk of ovarian cancer.

30. Despite this information, Defendants have not and do not warn or inform the Public anywhere, including on the product labeling or in their marketing or advertising for the products, that the use of their Talc Products in the genital area increases the risk of contracting ovarian cancer or even that there are certain studies that demonstrate the association between the use of talc powders and ovarian cancer.

31. To the contrary, Defendants have marketed their products as safe for human use. Historically, Johnson's Baby Powder® was marketed as a symbol of freshness, cleanliness, and purity. During the time in question, Defendants advertised and marketed their product as the beacon of "freshness" and "comfort," eliminating friction on the skin, absorbing "excess wetness" helping keep skin feeling dry and comfortable, and "clinically proven gentle and mild." Defendants persuaded women through advertisements to dust themselves with their product to mask odors. The bottle of Johnson's Baby Powder® specifically targets women by stating, "For you, use every day to help feel soft, fresh, and comfortable."

32. During the time in question, Defendants advertised and marketed their product Shower to Shower® as safe for use by women as evidenced in its slogan, "A sprinkle a day keeps odor away," and through advertisements such as: "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel, dry, fresh and comfortable throughout the day" and "SHOWER to SHOWER can be used all over your body."

33. As a result of Defendants' advertising, marketing, and labeling of the Talc Products, dusting the perineum for feminine hygiene was an intended and foreseeable use of Defendants' products. However, Defendants never warned or informed the residents of Mississippi anywhere that the Talc Products were unsafe for human use.

B. DEFENDANTS KNEW OR SHOULD HAVE KNOWN THE TALC PRODUCTS WERE UNSAFE

34. Defendants publicly and internally recognized the numerous studies linking the use of their products to ovarian cancer. Since the 1960s, study after study has shown that particles similar to talc can translocate from exterior genital areas to the ovaries with perineal use. With such translocation, researchers found the products containing talc, like Defendants' Talc Products, caused the growth of epithelial tissue. Finally, in 1982, a study funded by the National Institutes of Health and conducted by Dr. Daniel Cramer of Brigham and Women's Hospital was published that concluded women were three (3) times more likely to contract ovarian cancer after daily use of talcum powder in the genital area. Cramer, D.W.; Welch, W.R.; Scully, R.E.; Wojciechowski, C.A., "Ovarian cancer and talc: a case control study." Cancer 1982; 50: 372-376, 1982.

35. Defendants took steps to neutralize the study's effects. Soon after this study was published, Dr. Cramer was contacted and visited by Dr. Bruce Semple from Johnson & Johnson. Dr. Cramer's response was to advise Dr. Semple to place a warning on his company's talc-based body powders regarding the increased risk of ovarian cancer. Rather than acknowledge the concerns raised by Dr. Cramer's study, on August 12, 1982, in a New York Times article entitled "Talcum Company Calls Study on Cancer Link Inconclusive," Defendants admitted being aware of the study's conclusions but dismissed its findings and declined to provide the requested warnings.

36. Over the ensuing years, additional evidence of the health risks associated with talc continued to build. On November 10, 1994, the Cancer Prevention Coalition ("CPC") mailed a letter to Ralph Larson, then Defendants' C.E.O, informing Defendants that studies as far back as the 1960's ". . . show[] conclusively that the frequent use of talcum powder in the genital area

poses a serious risk of ovarian cancer." The letter cited a contemporaneous study by Dr. Bernard Harlow from Harvard Medical School confirming this fact and quoted a portion of the study where Dr. Harlow and his colleagues discouraged the use of talc in the female genital area. The letter further stated that 14,000 women per year die from ovarian cancer and that this type of cancer is very difficult to detect and has a low survival rate. The letter concluded by requesting that Defendants withdraw the Talc Products from the market because of the alternative of cornstarch powders, or at a minimum, place warning information on its talc-based body powders about the ovarian cancer risk they pose. Despite this evidence, Defendants refused.

37. On September 17, 1997, Alfred Wehner, a toxicology consultant retained by Defendants, wrote a letter to Michael Chudkowski, manager of Pre-Clinical Toxicology at JJCC, Inc., stating that on three separate occasions the Talc Interested Party Task Force ("TIPTF") of the CTFA, which included Defendants, had released false information to the public about the safety of talc. Specifically addressing a November 17, 1994 statement released by the CTFA, Dr. Wehner said the following:

> The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.
>
> The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper Debra Heller, and others.

38. On February 26, 2002, Imerys, which admittedly supplies all of the talc to Defendants for their Talc Products, wrote in its internal memorandum entitled "NTP Talc Review Status," "Specific Litigation Issues & Problems" the following:

> Listing of "talc not containing asbestos fibers" could be potentially devastating from a product liability perspective. [Plaintiff's attorney: "So Mr. Zazenski, please tell the Court when Luzenac [Imerys] first learned that talc was possibly associated with ovarian cancer?" "When did you first start warning consumers that this association was possible and under study." "Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the 'women and children in our society?'" Etc. etc. etc.]

39. In 2002, E. Edward Kavanaugh, the President of the CTFA, wrote a letter to Dr. Kenneth Olden, Director of the National Toxicology Program ("NTP") and National Institute of Environmental Health Sciences, U.S. Department of Health and Human Services, in an attempt to stop the NTP from listing cosmetic talc as a carcinogen in the upcoming 10th Report on Carcinogens (RoC) Report. Defendants have been long-standing, active members and donors of the CTFA. The NTP had already nominated cosmetic talc for this classification. In this letter, the CTFA admitted that talc was "toxic," and that "some talc particles . . . can reach the human ovaries," and acknowledged and agreed that prior epidemiologic studies have concluded that talc increases the risk of ovarian cancer in women.

40. In February of 2006, the International Association for the Research of Cancer ("IARC"), part of the World Health Organization, published a paper whereby it classified perineal use of talc-based body powder as a "Group 2B" possible human carcinogen. IARC, which is universally accepted as the international authority on cancer issues, concluded that studies from around the world consistently found an increased risk of ovarian cancer in women

from perineal use of talc. IARC found that between 16% - 52% of women in the world use talcum powder to dust their perineum and found an increased risk of ovarian cancer in women talc-users ranging from 30% - 60%.

41. IARC concluded with this "Evaluation:" "There is limited evidence in humans for the carcinogenicity of perineal use of talc-based body powder." By definition, "Limited evidence of carcinogenicity" means "a positive association has been observed between exposure to the agent and cancer for which a causal interpretation is considered by the Working Group to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence." IARC concluded with this "Overall evaluation:" "Perineal use of talc-based body powder is possibly carcinogenic to humans (Group 2B)."

42. Within months of the IARC's finding, Imerys began placing an ovarian cancer warning on the Material Safety Data Sheets ("MSDS") that it provided to Defendants with the non-asbestiform talc[2] it was producing.[3] These MSDSs not only provided Defendants with the warning information about the IARC classification, but they also included warning information regarding "States Rights to Know" and warning information about the Canadian Government's "D2A" classification of talc as a "very toxic," and a "cancer causing" substance as well. Defendants never passed this warning information on to their consumers

43. On July 12, 2006, Eric Turner, Vice-President of Health, Safety and Environment of Luzenac America, Inc. (Imerys), wrote a letter to Mark Ellis, President of Industrial Minerals Association – North America explaining why the "talc interested parties," which included

[2] Asbestiform talc, i.e., talc containing asbestos-like fibers, has not been used in cosmetic talc products since the 1970s. Defendants have acknowledged that the Talc Products at issue here have not been made with asbestiform talc for decades.

[3] On September 26, 2012, the corporate representative of Imerys testified that his company exclusively supplied Defendants with talc used for its Talc Products. He further testified that ovarian cancer is a potential hazard associated with a women's perineal use of talc-based body powders.

Defendants and Luzenac America, Inc. (Imerys), were foregoing further funding on a talc study called the "Mossman Study." Mr. Turner wrote: "When IARC concluded their review and classified 'perineal use of talc-based powders' as a Group 2b carcinogen, we began to question the value of proceeding any further with the Mossman study. To put it in the vernacular, the 'horse has already left the barn.'" Mr. Turner further wrote: "The cosmetic and pharmaceutical companies engaged in the business of marketing dusting and body powders to the public and show (sic) no enthusiasm for sponsoring new research on this issue." Mr. Turner noted that: "One of their primary arguments is that there are simply too many positive epidemiology studies published to stem the tide of negative sentiment." Mr. Turner concluded that: "Supplying talc for the body powder market is a rather insignificant element in our overall product portfolio and does not warrant any further sponsorship for research projects to support the business."

44. More recently, the CPC has been increasingly concerned about the link between talc-containing products and ovarian cancer. In May 2008, the CPC, joined by its chairman and numerous other physicians and chairs of public health and medical associations,[4] submitted a citizen's petition "seeking a cancer warning on cosmetic talc products." Specifically, the petition sought to require all cosmetic talc products to bear labels with warnings such as, "[f]requent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer" or "[f]requent talc application in the female genital area ***is responsible*** for major risks of ovarian cancer." (Emphasis added). The petition cited numerous studies and publications and sought a hearing to present scientific evidence.

[4] The petition was submitted on behalf of: Samuel S. Epstein, M.D., Chairman, CPC, and Professor Emeritus Occupational and Environmental Medicine, University of Illinois at Chicago School of Public Health; Peter Orris, M.D., Professor and Chief of Service, University of Illinois at Chicago Medical Center; Quentin Young, M.D., Chairman, Health and Medicine Policy Research Group, Chicago; Rosalie Bertell, Ph.D., International Association for Humanitarian Medicine, Scientific Advisor to the International Institute of Concern for Public Health, Toronto, and the International Science Oversight Board of the Organic Consumers Association, Washington, D.C.; and Ronnie Cummins, National Director of the Organic Consumers Association.

45. Based on solid evidence, the National Cancer Institute (NCI) lists perineal use of talc as a "risk factor" for ovarian cancer.

46. Despite this knowledge, the talc industry, including Defendants, has resisted making the public aware of the relationship between talc and cancer. On October 4, 2013, a jury in South Dakota Federal Court, in the case styled *Deane Berg v. Johnson & Johnson Consumer Companies, Inc.,* unanimously found that Defendant Johnson & Johnson Consumer Companies, Inc. caused the Plaintiff's ovarian cancer and was negligent in failing to warn about cancer hazards on its talc-based body powders, specifically, Baby Powder® and Shower to Shower®.

C. DECADES OF EPIDEMIOLOGIC STUDIES DEMONSTRATE THE SCIENTIFIC LINK BETWEEN TALC AND CANCER

47. For more than 30 years, study after study has concluded that perineal talc use by women is associated with an increased risk of ovarian cancer. Despite this, Defendants have never informed the Public about the potentially lethal consequences associated with talc, and continually advertised and marketed talc as safe for human use. However, research done as early as 1961 has shown that particles, similar to talc, can translocate from the exterior genital area to the ovaries in women. Egli GE, Newton M. "The transport of carbon particles in the human female reproductive tract." *Fertility Sterility* 1961; 12:151-155.

48. The first study to suggest a link between ovarian cancer and talc was a report by Henderson, *et al.*, who found talc particles "deeply embedded" in 10 of 13 ovarian tumors, 12 of 21 cervical tumors, one primary carcinoma of the endometrium, and 5 of 12 "normal" ovaries from women with breast cancer. Henderson, W.J.; Joslin, C.A.; Turnbull, A.C.; Griffiths, K.; "Talc and carcinoma of the ovary and cervix." *J. Obstet. Gynaecol. Br. Commonw.* 1971; 78(3): 266-272.

49. In 1968, a study concluded that: "all of the 22 talcum products analyzed have a … fiber content ... averaging 19%. The fibrous material was predominantly talc but contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits … Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem. Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo, RM. "Fibrous and mineral content of cosmetic talcum products." *Am. Industrial Hygiene Assoc. J.* 1968; 29:350-354.

50. In 1976, a follow-up study to these findings was conducted that examined 21 samples of consumer talcum powders, including baby powders, on the market between 1971 and 1975. The study concluded that: "The presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc. . .We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products." Rohl AN, Langer AM, Selifoff IJ, Tordini A, Klimentidis R, Bowes DR, Skinner DL. "Consumer talcums and powders: mineral and chemical characterization." *J. Toxicol. Environ. Health* 1976; 2:255-284.

51. As noted above, in the mid-1970s, in response to concerns about cancer risks associated with talc, manufacturers of cosmetic talc products stopped using asbestiform talc.

52. Still, years after the industry stopped using asbestiform talc, evidence continued to mount of the increased risk of ovarian cancer associated with cosmetic talc use. In 1982, a case-control study, funded by a grant from National Institutes of Health ("NIH"), was conducted by Daniel Cramer of the Departments of Obstetrics, Gynecology, and Pathology, Boston

Hospital for Women, Division of the Brigham and Women's Hospital, the Department of Epidemiology, Harvard School of Public Health and the Department of Pathology, Massachusetts General Hospital, Harvard Medical School. This study found that talc applied directly to the genital area around the time of ovulation leads to talc particles becoming deeply imbedded in the substance of the ovary, causing foreign body reaction and growth of epithelial ovarian tissue. The study ultimately found a statistically significant 92% increased risk of ovarian cancer from genital talc use. This study proved an epidemiologic association between the use of cosmetic talc in genital hygiene and ovarian cancer. Cramer, D.W.; Welch, W.R.; Scully, R.E.; Wojciechowski, C.A. "Ovarian cancer and talc: a case control study." *Cancer* 1982; 50: 372-376.

53. Since 1982, there have been 21 additional studies by different doctors and scientists throughout the world, including 19 case-control studies, 1 cohort study, and 1 combined case-control and cohort study, which have provided epidemiologic data addressing the talc and ovarian cancer association. Nearly all of these studies have reported an elevated risk for ovarian cancer associated with genital talc use and the majority statistically significant elevations.

54. In 1983, Patricia Hartge and Robert Hoover of the National Cancer Institute, along with Linda Lesher and Larry McGowan of the George Washington University Medical Center, performed a case-control study that found a 150% increased risk of ovarian cancer for women who use talcum powder in the genital area. Hartge, P; Hoover, R.; Lesher, L.P.; McGowan, L. "Talc and ovarian cancer." *JAMA,* 1983; 250(14): 1844.

55. From 1988 to 1992, cancer research in the United States found repeatedly that frequent talcum powder application in the genital area increases a woman's risk of developing

ovarian cancer. Hartge P, Hoover R, Lesher LP, McGowan L. "Talc and ovarian cancer." Letter JAMA 1983; 250: 1844; Whittemore AS, Wu ML, Paftenbarger, RS, Sarles DL, Kampert JB, Grosser S, Jung DEL, Ballon S, Hendrickson M. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures talcum powder, tobacco, alcohol, and coffee." *Am. J. Epidemiol.* 1988; 1128: 1228-1240; Rosenblatt KA, Szklo M, Rosenshein NB. " Mineral fiber exposure and the development of ovarian cancer." *Gynecol. Oncol.* 1992; 45:20-25; Harlow BL, Cramer DW, Bell DA, Welch WR. "Perineal exposure to talc and ovarian cancer risk." *Obstet. Gynecol.* 1992; 80: 19-26.

56. In 1988, Alice Whittemore, and several others, performed a case control study of 188 women diagnosed with epithelial ovarian cancer with 539 control women. This study found that 52% of the cancer patients habitually used talcum powder on the perineum. The study showed a 40% increase in risk of ovarian cancer in women that used talcum powder on their perineum. This study also showed a positive dose-response relationship. Whittemore, A.S.; Wu, M.L.; Paffenbarger, R.S., Jr.; et al. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee." *Am. J. Epidemiol.* 1988; 128 (6): 1228-1240.

57. In 1989, a case control study conducted in England of 235 women diagnosed with epithelial ovarian cancer and 451 controls found a 29% increased risk in ovarian cancer with women who reported genital talcum powder use more than once per week. Booth, M.; Beral, V.; Smith, P.; "Risk factors for ovarian cancer: a case-control study." *Br. J. Cancer.* 1989; 60 (4): 592-598.

58. In 1989, a case control study was conducted by Bernard Harlow of Harvard Medical School at Brigham and Women's Hospital, which found an increased risk of ovarian

cancer generally from genital talcum powder use after bathing, and found a statistically significant 180% increased risk of ovarian cancer from women that used talc-containing powders in combination with deodorizing powders on their perineum. This study also found a positive dose-response relationship. Harlow, B.L.; Weiss, N.S. "A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc." *Am. J. Epidemiol.* 1989; 130 (2): 390-394.

59. Five separate meta-analyses were also conducted on the topic of talcum powder use and ovarian cancer. A meta-analysis is a statistical technique that allows similar measures of the same illness and exposure from different studies to be combined to determine whether an association exists. All five analyses found a significant positive association between the use of talcum powder in the genital area and ovarian cancer.

60. In 1992, Bernard Harlow and Daniel Cramer from Harvard Medical School at Brigham and Women's Hospital conducted the first meta-analyses that included the odds ratio from a new series of 235 cases with ovarian cancer and 239 controls and 5 other published studies sponsored by the National Cancer Institute ("NCI"). The study was considered the most comprehensive study of talc use and ovarian cancer to date. The summary OR (and 95% confidence interval) was 1.3 (1.1, 1.6) indicating a statistically significant 30% increased risk of ovarian cancer from genital talcum powder use. The conclusion from this study was that "a lifetime pattern of talc use may increase the risk for epithelial ovarian cancer. . . ." Harlow, B.L.; Cramer, D.W.; Bell, D.A.; Welch, W.R. "Perineal exposure to talc and ovarian cancer risk." *Obstet. Gynecol.* 1992; 45 (1): 20-25.

61. The study also found that the most frequent method of talcum powder exposure was to use it as a dusting powder directly to the perineum (genitals). "Brand or generic 'baby

powder' was used most frequently and was the category associated with a statistically significant risk for ovarian cancer." Through personal interviews with these women, Harlow and his team found that nearly 17% of the control group reported frequent talcum powder application to the perineum. This study concluded that "…. given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit." Harlow, B.L.; Cramer, D.W.; Bell, D.A.; Welch, W.R. "Perineal exposure to talc and ovarian cancer risk." *Obstet. Gynecol.* 1992; 80 (1): 19-26.

62. In 1992, Karin Rosenblatt, among others, conducted a case-control study from the Department of Epidemiology, the Johns Hopkins School of Hygiene and Public Health, and Department of Gynecology and Obstetrics. This was a hospital case-control study that found a 70% increased risk of ovarian cancer in women from genital talcum powder use, and a 379% increased risk of ovarian cancer in women who used talc on sanitary napkins in their genital area. Rosenblatt, K.A.; Szklo, M.; Rosenshein, N.B. "Mineral fiber exposure and the development of ovarian cancer." *Gynecol. Oncol.* 1992; 45 (1): 20-25.

63. Yong Chen, *et al.,* conducted a case-control study in 1992 of 112 diagnosed epithelial ovarian cancer cases and 224 age-matched community controls. The study found an elevated risk of 290% for ovarian cancer for women who applied talc-containing dusting powder to the lower abdomen and perineum for longer than 3 months. Yong Chen; Pao-Chen Wu; Jeng-He Lang; Wen-Jun Ge; Hartge, P.; and Brinton, L.A. "Risk Factors for Epithelial Ovarian Cancer in Beijing, China." *Int. J. Epidemiol.* 1992; (21 (1): 23-29.

64. In 1993, the United States National Toxicology Program published a study on the toxicity of non-asbestiform talcum powder that found clear evidence of carcinogenic activity.

Talcum powder was found to be a carcinogen, with or without the presence of asbestos-like fibers. National Toxicology Program. "Toxicology and carcinogenesis studies of talc (CAS No 14807-96-6) in F344/N rats and B6C3F 1 mice (Inhalation studies)." *Technical Report Series No. 421,* September 1993.

65. David Purdie conducted a case control study in 1995 involving over 1,600 women, the largest study of its kind to date. This study found a statistically significant 27% increased risk in ovarian cancer for women who regularly use talcum powder in the region of the abdomen or perineum. Purdie, D.; Green, A.; Bain, C.; et al. "Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study. Survey of Women's Health Study Group." *Int. J. Cancer.* 1995; 62 (6): 678-684.

66. In 1995, a second meta-analysis was conducted by A.J. Gross and P.H. Berg and included data from nine separate papers. This meta-analysis yielded a summary odds ratio (based upon the crude measures) of 1.27 (1.09, 1.48) – again a statistically significant 27% increased risk of ovarian cancer from genital talc use. Gross, A.J.; Berg, P.H. "A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer." *J. Expo. Anal. Environ. Epidemiol.* 1995; 5 (2): 181-195.

67. In 1996, a case-control study was conducted by Asher Shushan, which found a statistically significant 97% increased risk of ovarian cancer in women who used talc-based powders in their genital area. Shushan, A.; Paltiel, O.; Iscovich, J.; Elchalal, U.; Peretz, T.; Schenker, J.G., "Human menopausal gonadotropin and the risk of epithelial ovarian cancer." *Fertil. Steril.* 1995; 65 (1): 13-18.

68. In 1996, the condom industry stopped dusting condoms with talcum powder due to the health concerns of ovarian cancer. "Concern about talc as an ovarian carcinogen goes

back 50 years in the medical literature. By the 1970s, evidence was mounting that talc particles might migrate into a woman's fallopian tubes where they could cause scarring and irritation in the ovaries. Scientists believed in some cases that the scarring led to infertility or cancer." McCullough, Marie, "Women's health concerns prompt condom makers to stop using talc." *Jersey Journal (City Edition)*, April 17, 1996.

69. In 1997, a case control study of 313 women with ovarian cancer and 422 without this disease found that the women with cancer were more likely to have applied talcum powder to their external genitalia area. Women using these products had a statistically significant 50% to 90% higher risk of developing ovarian cancer. Cook, L.S.; Kamb, M.L.; Weiss, N.S. "Perineal powder exposure and the risk of ovarian cancer." *Am. J. Epidemiol.* 1997; 145: 459-465.

70. In 1997, a case-control study was conducted by Stella Chang and Harvey Risch from the Department of Epidemiology and Public Health at the Yale University School of Medicine, which included over 1,000 women. The study found a statistically significant increased risk of 42% for ovarian cancer for women who applied talc via sanitary napkins to their perineum. The study indicated, "Commercial talc substitutes often replace talc with cornstarch. Furthermore, women may choose to powder or dust with cornstarch instead of talc. When cornstarch was assessed in relation to risk of ovarian carcinoma, no associations were found." The study concluded, "The results of this study appear to support the contention that talc exposure increases risk of ovarian carcinoma. Dusting with talcum powder is not an unusual practice for women, and, given the heterogeneity of the etiology and course of ovarian carcinoma, any possible harmful practices, particularly those with little benefit, should be

deliberated." Chang, S.; Risch, H.A. "Perineal talc exposure and risk of ovarian carcinoma." *Cancer.* 1997; 79 (12): 2396-2401.

71. In 1998, Beatrice Godard conducted a case-control study that found a 149% increased risk of ovarian cancer in women who used talc-based powders on their perineum. Godard, B.; Foulkes, W.D.; Provencher, D.; et al., "Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study." *Am. J. Obstet. Gynecol.* 1998; 179 (2): 403-410.

72. In 1999, Dr. Daniel Cramer, conducted another case-control study funded by a grant from the NCI. This study included 563 women newly diagnosed with epithelial ovarian cancer and 523 control women. The study found a statistically significant 60% increased risk of ovarian cancer in women that used talc-based body powders on their perineum. "We conclude that there is a significant association between the use of talc in genital hygiene and risk of epithelial ovarian cancer that, when viewed in perspective of published data on this association, warrants more formal public health warnings." Cramer, D.W.; Liberman, R.F.; Titus-Ernstoff, L.; et al. "Genital talc exposure and risk of ovarian cancer." *Int. J. Cancer.* 1999; 81 (3): 351-356.

73. Also in 1999, Daniel Cramer performed a third meta-analysis supported by a grant from the NCI. It included all of the studies in the Gross and Berg meta-analysis plus four new studies, as well as the odds ratio (OR) based upon a new series of 563 cases with ovarian cancer and 523 controls from Massachusetts and New Hampshire. The summary odds estimate was 1.39 (1.24, 1.49), again, a statistically significant 39% increased risk of ovarian cancer from genital talcum powder use.

74. In 2000, Roberta Ness, from the University of Pennsylvania, produced a case-control study of over 2,000 women. This study found a statistically significant 50% increased risk of ovarian cancer from genital talc use in women. The study also found that talcum powder causes inflammation and that inflammation contributes to cancer cell development. Ness, R.B.; Grisso, J.A.; Cottreau, C.; et al. "Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology.* 2000; 11 (2): 111-117.

75. A prospective cohort study conducted in 2000, and considered the most informative study to date, found a 40% increase in invasive serous cancers from women who applied talcum powder to their perineum. Gertig, D.M.; Hunter, D.J.; Cramer, D.W.; Coditz, G.A.; Speizer, F.E.; Willett, W.C.; Hankinson, S.E. "Prospective study of talc use and ovarian cancer." *J. Natl. Cancer Inst.;* 2000; 92: 249-252.

76. In 2003, a fourth meta-analysis was conducted that re-analyzed data from 16 studies published prior to 2003 and found a 33% increase in ovarian cancer risk among talcum powder users. This study was funded by industry players. Huncharek, M.; Geschwind, J.F.; Kupelnick, B. "Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: a meta-analysis of 11,933 subjects from sixteen observational studies." *Anticancer Res.* 2003; 23: 1955-60.

77. In 2004, Paul Mills, Deborah Riordan, Rosemary Cress, and Heather Young of the Cancer Registry of Central California – Public Health Institute in Fresno, California; the Fresno Medical Education Program at the University of California in San Francisco, California; the California Cancer Registry in Sacramento, California; and the Department of Epidemiology and Biostatistics at George Washington University School of Public Health and Health Services in Washington, D.C., performed a case-control study of nearly 1400 women from 22 counties in

Central California and found a statistically significant 37% increased risk of epithelial ovarian cancer from women's genital talcum powder use. The study also found a 77% increased risk of serous invasive ovarian cancer from women's genital talcum powder use. The study looked at cornstarch powders and found no increased risk in ovarian cancer in women who used these types of powders on the perineum as "Cornstarch is also not thought to exert the same toxicologic reaction in human tissue as does talc." This study concluded by stating, ". . . users should exercise prudence in reducing or eliminating use. In this instance, the precautionary principle should be invoked, especially given that this is a serious form of cancer, usually associated with a poor prognosis, with no current effective screening tool, steady incidence rates during the last quarter century and no prospect for successful therapy. Unlike other forms of environmental exposures, talcum powder use is easily avoidable." Mills, P.K.; Riordan, D.G.; Cress, R.D.; Young H.A. "Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California." *Int. J. Cancer.* 2004; 112:458-64.

78. This study found a 54% increased risk in ovarian cancer from talcum powder use in women who had not undergone a tubal ligation, whereas the study found no impact on women who had their tubes tied. Because it had been found in previous studies that talc particles migrate up the fallopian tubes in women, this finding provided strong evidence to support the idea that talc is a carcinogen. *Id.*

79. In 2005, the Fifth Edition of "Myths & Facts about ovarian cancer: What you need to know," was published by Steven Piver, M.D. and Gamal Eltabbakh, M.D. This publication was partly sponsored by Glaxo Smith Kline. Dr. Piver is the Chair Emeritus of the Department of Gynecologic Oncology, and Founder and Director of the Gilda Radner Familial Ovarian Cancer Registry at Roswell Park Cancer Institute in Buffalo, New York. Dr. Eltabbakh

is a tenured Professor of Obstetrics and Gynecology and Medicine, and Director of the Division of Gynecologic Oncology at the University of Vermont in Burlington, Vermont. In the section entitled: "What Causes Ovarian Cancer?" it lists "Use of Talc (Baby Powder) in the Genital Area" as a risk factor for causing ovarian cancer and further states, "… research has established that each has at least a small role" in causing cancer in women. M. Steven Piver, et al. "Myths & Facts about ovarian cancer: What you need to know." *CMP Medica.* 2007 5th Ed.

80. In 2006, in addition to IARC's classification of perineal use of talc-based body powder as a "Group 2B" possible human carcinogen, the Canadian government, under The Hazardous Products Act and associated Controlled Products Regulations classified talc as a "D2A", "very toxic", "cancer causing" substance under its Workplace Hazardous Materials Information System (WHMIS). As a point of reference, asbestos is also classified as "D2A."

81. In 2007, Amber Buz'Zard and Benjamin Lau performed a study whereby they induced carcinogenesis by applying talc to normal human epithelial and granulosa ovarian cancer cell lines. Buz'Zard A.R.; Lau, B.H., "Pycnogenol reduces talc-induced neoplastic transformation in human ovarian cell cultures." *Phytother. Res.* 2007; 21 (6): 579-586.

82. In 2008, Margaret Gates, of Channing Laboratory, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School; Departments of Epidemiology and Biostatistics, Harvard School of Public Health; Obstetrics and Gynecology Epidemiology Center, Brigham and Women's Hospital, and Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, performed a combined study of over 3,000 women from a New England based case-control study and a prospective Nurses' Health Study that included additional cases and years of follow up from these studies (the "Gates Study"). This study was funded by the NCI, and found a general 36% statistically significant increased risk of epithelial

ovarian cancer from genital talcum powder use. A 60% increased risk of the serous invasive subtype was also found. This study found a strong and positive dose-response relationship whereby increased risk was seen with higher talcum powder usage in women.

83. Dr. Gates commented about this study saying these latest results "provide additional support for a main effect of genital talc exposure on epithelial ovarian cancer." She also stated that "…the finding of highly significant trends between increasing frequency of use and risk 'strengthens the evidence of an association, because most previous studies have not observed a dose response.'" She noted that: "We believe that women should be advised not to use talcum powder in the genital area, based on our results and previous evidence supporting an association between genital talc use and ovarian cancer risk. Physicians should ask the patient about talc use history and should advise the patient to discontinue using talc in the genital area if the patient has not already stopped." Dr. Gates further stated that: "An alternative to talc is cornstarch powder, which has not been shown to increase ovarian cancer risk, or to forgo genital powder use altogether." Gates, M.A.; Shelley, S.; Tworoger, S.S.; Terry, K.L.; Titus-Ernstoff, L.; *et al.* "Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer." *Cancer Epidemiology, Biomarkers & Prev.* 2008; 17 (9): 2436-2444.

84. In October of 2008, Michael Thun, Vice-President of Epidemiology and Surveillance Research at the American Cancer Society, commented on the Gates Study. He stated this study demonstrates the dose-response relationship between talcum powder and ovarian cancer. Dr. Thun stated: "There are very few modifiable risk factors for ovarian cancer. The main one is the use of oral contraceptives, which has been clearly established to lower the risk for ovarian cancer. Others include tubal ligation, hysterectomy, and parity. Then, there are factors that 'probably' increase the risk for ovarian cancer, and this is where talc fits in,

alongside asbestos, postmenopausal hormone therapy, and radiation." Chustecka, Zosia; Lie, Desiree, "Talc Use in Genital Area Linked to Increased Risk for Ovarian Cancer," *Medscape Medical News,* 2008.

85. In 2008, Melissa Merritt conducted a case-control study of over 3,000 women for the Australian Cancer Study (Ovarian Cancer) and Australian Ovarian Cancer Study Group, which confirmed a statistically significant 17% increased risk of ovarian cancer for women who used talcum powder on their perineum. This study also confirmed a statistically significant 21% increased risk of ovarian cancer of a serous subtype in women who used talc on their perineum. Merritt, M.A.; Green, A.C.; Nagle, C.M.; Webb, P.M., "Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer." *Int. J. Cancer.,* 2008; 122 (1):170-176.

86. In 2009, Anna Wu, among others, conducted a case-control study of over 1,200 women and found the risk of ovarian cancer increased significantly with increasing frequency and duration of talcum powder use. The study found an overall statistically significant 53% increased risk of ovarian cancer from genital talcum powder use. The study also found a statistically significant 108% increased risk of ovarian cancer in women with the longest duration and most frequent talc use. The study concluded by stating, ". . . [the] risk of ovarian cancer is significantly associated with talc use and with a history of endometriosis, as has been found in recent studies." Wu, A.H.; Pearce, C.L.; Tseng, C.C.; Templeman, C.; Pike, M.C., "Markers of inflammation and risk of ovarian cancer in Los Angeles County," *Int. J. Cancer.* 2009; 124 (6): 1409-1415.

87. In 2011, Dr. Daniel Cramer of Brigham and Women's Hospital, Harvard Medical School, made public a case-control study of over 4,000 women funded by the NCI. This study

found a 200% to 300% increased risk of ovarian cancer for women who applied talc-based body powders to their perineum. This study found a strong dose-response relationship. In commenting on this study, Dr. Cramer stated, "I have always advised gynecologists, if they examine a woman and see that she is using talc in the vaginal area, tell her to stop … There are alternatives. This study strongly reinforces that advice."

88. In 2011, Karin Rosenblatt and several other authors conducted a case-control study of over 2,000 women that found a 27% increased risk of ovarian cancer from genital talcum powder use in women. Rosenblatt, K.A.; Weiss, N.S.; Cushing-Haugen, K.L.; Wicklund, K.G.; Rossing, M.A., "Genital powder exposure and the risk of epithelial ovarian cancer," *Cancer Causes Control.* 2011; 22(5): 737-742.

89. In June of 2013, Kathryn Terry published a pooled analysis of over 18,000 women in eight case-control studies and found a 20% to 30% increased risk of women developing epithelial ovarian cancer from genital talcum powder use. The study concluded by stating, "Because there are few modifiable risk factors for ovarian cancer, avoidance of genital powders may be a possible strategy to reduce ovarian cancer incidence." Terry, K.L.; Karageorgi, S.; Svetsov, Y.B.; Merritt, M.A.; Lurie, G.; et al., "Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls," *Cancer Prevention Research* 2013; 6: 811-821.)

90. The National Cancer Institute (NCI)'s website currently lists perineal talcum powder use as a "risk factor" for ovarian cancer based on "solid evidence."

91. Defendants knew or should have known of the hazards associated with the use of their Talc Products.

92. Defendants had and continue to have a duty to warn about the hazards associated with the use of their Talc Products. Defendants have failed and continue to fail to inform the Public of the known catastrophic health consequences associated with the use of their Talc Products.

93. In addition, Defendants purposely procured and disseminated false, misleading, and deceptive information regarding the safety of the Talc Products to the public and specifically targeted minority communities in selling the Talc Products.

94. The public has been and will continue to be deceived and/or misled by Defendants' omissions and deceptive representations that the Talc Products are safe for women to use in the genital area. The risk of ovarian cancer, which is often fatal, far outweighs any benefit of the cosmetic use of the Talc Products, especially when non-talc products are readily available and equally effective as the Talc Products.

V. CAUSE OF ACTION
Violations of the Mississippi Consumer Protection Act
Miss. Code Ann. §§ 75-24-1. et seq.

95. The State hereby repeats, incorporates by reference, and realleges each and every allegation set forth in this Complaint.

96. Defendants engaged in unfair methods of competition and unfair and deceptive trade practices in or affecting commerce in violation of Miss. Code Ann. §§ 75-24-5(1) and (2):

a. in the course of trade or commerce, Defendants misrepresented their goods as having uses and/or benefits that they do not have in violation of Miss. Code Ann. § 75-24-5(2)(e);

b. in the course of trade or commerce, Defendants misrepresented their goods as having qualities and/or standards that they did not have in violation of Miss. Code Ann. § 75-24-5(2)(g);

c. Defendants actively promoted, advertised and marketed their products by disseminating misrepresentations and omissions to Mississippi consumers, focusing on certain minority communities;

d. the State seeks an injunction preventing Defendants from deceptively marketing their Talc Products, requiring disgorgement of ill-gotten revenue obtained as a result of that deceptive marketing, and any other remedies the Court deems appropriate pursuant to Miss. Code Ann. §§ 75-24-9 and 75-24-11;

e. the State seeks investigative costs and attorneys' fees pursuant to Miss. Code Ann. § 75-24-19(b); and,

f. the State seeks civil penalties pursuant to Miss. Code Ann. § 75-24-19(1)(b) because Defendants knowingly and willfully used unfair and deceptive trade practices. The State seeks such additional relief pursuant to Miss. Code Ann. §§ 75-24-11 and 75-24-5 as the Court may determine is warranted under the facts presented.

VI. PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff Attorney General Jim Hood on behalf of the State of Mississippi prays for the following relief from this Honorable Court:

1. a finding by the Court that, by the acts and omissions alleged herein, Defendants engaged in unfair and deceptive business acts and practices in the course of engaging in commerce within the State of Mississippi in violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-1, *et seq.;*

2. an award of actual damages to the State in such amount as is proven at trial, together with prejudgment interest;

3. punitive damages;

4. an injunction requiring Defendants to warn of the hazards associated with the use of the Talc Products, to remove all products that fail to warn of the hazards associated with the product, and to prevent the continued violation of the Mississippi Consumer Protection Act;

5. an order pursuant to Miss. Code Ann. § 75-24-9 and § 75-24-11 requiring that Defendants submit to an accounting to determine the amount of improperly obtained revenue that was paid to Defendants for sale of their dangerous and defective Talc Products as a result of their unfair and deceptive trade practices, acts, and omissions, and to disgorge those ill-gotten revenues;

6. an order pursuant to Miss. Code Ann. § 75-24-19(1)(b) directing Defendants to pay a civil penalty of up to but not to exceed Ten Thousand Dollars ($10,000.00) for each and every violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-5;

7. an order directing Defendants to pay attorneys' fees, investigative costs and other costs of this action; and,

8. such other relief that this Court deems just and equitable under the law as may be proven at the trial of this matter.

RESPECTFULLY SUBMITTED, this the 22nd day of August, 2014.

PLAINTIFFS, STATE OF MISSISSIPPI, ex rel. JIM HOOD, ATTORNEY GENERAL

By: _____

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COVER SHEET

Civil Case Filing Form

(To be completed by Attorney/Party Prior to Filing of Pleading)

Mississippi Supreme Court — Form AOC/01
Administrative Office of Courts — (Rev 2009)

Court Identification Docket #: County # 25 | Judicial District 1 | Court ID CH (CH, CI, CO)
Case Year: 2014
Docket Number: 1207 GN (Local Docket ID)
Month 08 | Date 22 | Year 14
This area to be completed by clerk
Case Number if filed prior to 1/1/94

In the CHANCERY Court of HINDS County — 1st Judicial District

Origin of Suit (Place an "X" in one box only)

- [X] Initial Filing
- [ ] Remanded
- [ ] Reinstated
- [ ] Reopened
- [ ] Foreign Judgment Enrolled
- [ ] Joining Suit/Action
- [ ] Transfer from Other court
- [ ] Appeal
- [ ] Other

Plaintiff - Party(ies) Initially Bringing Suit Should Be Entered First - Enter Additional Plaintiffs on Separate Form

Individual: [redacted] Hood (Last Name) | Jim (First Name) | (Maiden Name, if applicable) | (M.I.) | (Jr/Sr/III/IV)

[ ] Check (x) if Individual Plaintiff is acting in capacity as Executor(trix) or Administrator(trix) of an Estate, and enter style:
Estate of

[X] Check (x) if Individual Plaintiff is acting in capacity as Business Owner/Operator (d/b/a) or State Agency, and enter entity:
D/B/A or Agency: Mississippi Attorney General

Business:
Enter legal name of business, corporation, partnership, agency - If Corporation, indicate the state where incorporated

[ ] Check (x) if Business Plaintiff is filing suit in the name of an entity other than the above, and enter below:
D/B/A:

Address of Plaintiff: 550 High St, Jackson, MS

Attorney (Name & Address): [redacted] Geoffrey Morgan, P.O. Box 220, Jackson, MS 39205 — MS Bar No. 3474

[ ] Check (x) if Individual Filing Initial Pleading is NOT an attorney

Signature of Individual Filing:

Defendant - Name of Defendant - Enter Additional Defendants on Separate Form

Individual: (Last Name) | (First Name) | (Maiden Name, if applicable) | (M.I.) | (Jr/Sr/III/IV)

[ ] Check (x) if Individual Defendant is acting in capacity as Executor(trix) or Administrator(trix) of an Estate, and enter style:
Estate of

[ ] Check (x) if Individual Defendant is acting in capacity as Business Owner/Operator (d/b/a) or State Agency, and enter entity:
D/B/A or Agency

Business: Johnson + Johnson
Enter legal name of business, corporation, partnership, agency - If Corporation, indicate the state where incorporated

[ ] Check (x) if Business Defendant is acting in the name of an entity other than the above, and enter below:
D/B/A:

Attorney (Name & Address) - If Known: — MS Bar No.:

Damages Sought: Compensatory $ _____ Punitive $ _____ [ ] Check (x) if child support is contemplated as an issue in this suit.*
*If checked, please submit completed Child Support Information Sheet with this Cover Sheet

Nature of Suit (Place an "X" in one box only)

Domestic Relations
- [ ] Child Custody/Visitation
- [ ] Child Support
- [ ] Contempt
- [ ] Divorce:Fault
- [ ] Divorce: Irreconcilable Diff.
- [ ] Domestic Abuse
- [ ] Emancipation
- [ ] Modification
- [ ] Paternity
- [ ] Property Division
- [ ] Separate Maintenance
- [ ] Termination of Parental Rights
- [ ] UIFSA (eff 7/1/97; formerly URESA)
- [ ] Other

Appeals
- [ ] Administrative Agency
- [ ] County Court
- [ ] Hardship Petition (Driver License)
- [ ] Justice Court
- [ ] MS Dept Employment Security
- [ ] Worker's Compensation
- [ ] Other

Chancery
- [ ] Accounting (Business)
- [ ] Business Dissolution
- [ ] Debt Collection
- [ ] Employment
- [ ] Foreign Judgment
- [ ] Garnishment
- [ ] Replevin
- [ ] Other

Probate
- [ ] Accounting (Probate)
- [ ] Birth Certificate Correction
- [ ] Commitment
- [ ] Conservatorship
- [ ] Guardianship
- [ ] Heirship
- [ ] Intestate Estate
- [ ] Minor's Settlement
- [ ] Muniment of Title
- [ ] Name Change
- [ ] Testate Estate
- [ ] Will Contest
- [ ] Other

Miscellaneous
- [ ] Adoption - Contested
- [ ] Adoption - Uncontested
- [ ] Consent to Abortion Minor
- [ ] Removal of Minority
- [ ] Other

Civil Rights
- [ ] Elections
- [ ] Expungement
- [ ] Habeas Corpus
- [ ] Post Conviction Relief/Prisoner
- [ ] Other

Contracts
- [ ] Breach of Contract
- [ ] Installment Contract
- [ ] Insurance
- [ ] Specific Performance
- [ ] Other

Eminent Domain/Condemnation
- [ ] Bond Validation
- [ ] Civil Forfeiture
- [ ] Declaratory Judgment
- [ ] Injunction or Restraining Order
- [ ] Other

Real Property
- [ ] Adverse Possession
- [ ] Ejectment
- [ ] Eminent Domain
- [ ] Eviction
- [ ] Judicial Foreclosure
- [ ] Lien Assertion
- [ ] Partition
- [ ] Tax Sale: Confirm/Cancel
- [ ] Title Boundary or Easement
- [ ] Other

Torts
- [ ] Bad Faith
- [ ] Fraud
- [ ] Loss of Consortium
- [ ] Malpractice - Legal
- [ ] Malpractice - Medical
- [ ] Mass Tort
- [ ] Negligence - General
- [ ] Negligence - Motor Vehicle
- [X] Product Liability
- [ ] Subrogation
- [ ] Wrongful Death
- [ ] Other

Exhibit C

Johnson Defendants' Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, Ex rel. JIM HOOD, ATTORNEY GENERAL

Civil Action No. 25CH1:14-cv-001207

PLAINTIFF,

v.

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC., VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

DEFENDANTS.

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.'S MOTION FOR SUMMARY JUDGMENT

Defendants Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Companies, Inc. ("JJCC"), by and through their undersigned counsel, pursuant to Rule 56 of the Mississippi Rules of Civil Procedure, respectfully request that summary judgment be entered in their favor and that the Complaint's claims as to them be dismissed with prejudice. In support thereof, and as set forth in the separately filed Memorandum of Law in Support, which is fully incorporated herein by reference, J&J and JJCC state as follows:

1. There is no genuine issue of material fact in dispute, and J&J and JJCC are entitled to a summary judgment as a matter of law.

2. The State's Complaint seeks an injunction from this Honorable Court under the Mississippi Consumer Protection Act ("MCPA") compelling J&J and JJCC to add additional language to the labeling of the talc products manufactured by JJCC – Johnson's Baby Powder and Shower to Shower.

3. Summary judgment is proper as a matter of law because the MCPA does not apply to the labeling of FDA-regulated products, including the "Talc Products" (Johnson's® Baby Powder, Shower to Shower®).

4. Summary judgment is also proper as a matter of law because, even if the MCPA did apply to these products, the State's claims are expressly and impliedly preempted by federal law.

5. In support of the motion and memorandum, J&J and JJCC submit the following exhibits:

Exhibit A: FDA/FTC Memorandum, 36 Fed. Reg. 18,539 September 16, 1971)

Exhibit B: Plaintiff's Responses to Defendant JJCC's First Set of Interrogatories

Exhibit C: FDA Letter Denying Citizen's Petitions (April 1, 2014).

Exhibit D: 1994 Citizen's Petition submitted by the Cancer Prevention Coalition

Exhibit E: 2008 Citizen's Petition submitted by the Cancer Prevention Coalition

CONCLUSION

For the foregoing reasons, J&J and JJCC respectfully request that summary judgment be entered in their favor and that the Complaint's claims as to them be dismissed with prejudice.

DATED: January 26, 2018

Respectfully submitted,

JOHNSON & JOHNSON and JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

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CERTIFICATE OF SERVICE

I, Meade M. Mitchell, one of the attorneys for J&J, do hereby certify that I have this day caused the foregoing to be electronically filed with the Clerk of the Court using the ECF system which sent notification of such filing to:

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Attorneys for Valeant Pharmaceuticals North America, LLC and Valeant Pharmaceuticals International, Inc.

THIS the 26th day of January, 2018.

/s/ *Meade W. Mitchell*
Meade W. Mitchell

Exhibit A

good cause by the Board or by the Federal Reserve Bank of Atlanta pursuant to delegated authority.

By order of the Board of Governors,[1] September 10, 1971.

[SEAL] TYNAN SMITH, *Secretary.*

[FR Doc.71-13595 Filed 9-15-71;8:45 am]

FIRST NATIONAL CHARTER CORP.

Notice of Application for Approval of Acquisition of Shares of Bank

Notice is hereby given that application has been made, pursuant to section 3(a)(3) of the Bank Holding Company Act of 1956 (12 U.S.C. 1842(a)(3)), by First National Charter Corporation, which is a bank holding company located in Kansas City, Mo., for prior approval by the Board of Governors of the acquisition by applicant of 80 percent or more of the voting shares of the Bank of Overland, Overland, Mo.

Section 3(c) of the Act provides that the Board shall not approve:

(1) Any acquisition or merger or consolidation under section 3 which would result in a monopoly, or which would be in furtherance of any combination or conspiracy to monopolize or to attempt to monopolize the business of banking in any part of the United States, or

(2) Any other proposed acquisition or merger or consolidation under section 3 whose effect in any section of the country may be substantially to lessen competition, or to tend to create a monopoly, or which in any other manner would be in restraint of trade, unless the Board finds that the anticompetitive effects of the proposed transaction are clearly outweighed in the public interest by the probable effect of the transaction in meeting the convenience and needs of the community to be served.

Section 3(c) further provides that, in every case, the Board shall take into consideration the financial and managerial resources and future prospects of the company or companies and the banks concerned, and the convenience and needs of the community to be served.

Not later than thirty (30) days after the publication of this notice in the FEDERAL REGISTER, comments and views regarding the proposed acquisition may be filed with the Board. Communications should be addressed to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The application may be inspected at the office of the Board of Governors or the Federal Reserve Bank of Kansas City.

Board of Governors of the Federal Reserve System, September 10, 1971.

[SEAL] TYNAN SMITH, *Secretary.*

[FR Doc.71-13596 Filed 9-15-71;8:45 am]

[1] Voting for this action: Vice Chairman Robertson and Governors Mitchell, Daane, Maisel, Brimmer, and Sherrill. Absent and not voting: Chairman Burns.

FEDERAL TRADE COMMISSION

MEMORANDUM OF UNDERSTANDING BETWEEN FEDERAL TRADE COMMISSION AND THE FOOD AND DRUG ADMINISTRATION

This Memorandum of Understanding updates and replaces:

a. "Working Agreement Between the Federal Trade Commission and the Food and Drug Administration—June 1954."

b. "Liaison Agreement Between the Federal Trade Commission and the Food and Drug Administration—January 23, 1968."

I. Purpose:

a. It is agreed that the common objective of preventing injury and deception of the consumer requires that the statutory authorities and procedures, and the manpower and other resources available to each agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both agencies in appropriate undertakings, and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefit to the public.

b. In order to provide for exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings and of internal developments in areas of joint concern to the extent that such information is not privileged.

II. *Designated liaison officers.*

a. *Federal Trade Commission.* The Assistant to the General Counsel of the Federal Trade Commission.

b. *Food and Drug Administration.* The Associate Commissioner for Compliance of the Food and Drug Administration.

III. In order to facilitate the purposes of this agreement, it is specifically agreed that:

a. With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs (with the exception of prescription drugs) devices, and cosmetics;

b. The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics;

c. The initiation of proceedings involving the same parties by both agencies shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required in instances where:

(1) The same, or similar claims are found in both labeling and advertising;

(2) Written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution;

(3) The article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

IV. It is further agreed that:

a. Regulations promulgated under section 5 of the Fair Packaging and Labeling Act by the respective agencies for the commodities for which they have jurisdiction under that Act, shall be as uniform as possible.

V. Meetings to be held:

a. The respective liaison officers will hold meetings from time to time to discuss matters of concern to each agency and that they will be accompanied by whatever staff they may deem appropriate and necessary.

VI. Period of agreement:

This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice.

Approved and accepted for the Food and Drug Administration: April 27, 1971.

CHARLES C. EDWARDS, *Commissioner of Food and Drugs.*

Approved and accepted for the Federal Trade Commission: May 14, 1971.

MILES W. KIRKPATRICK, *Chairman, Federal Trade Commission.*

By direction of the Commission dated September 9, 1971.

[SEAL] CHARLES A. TOBIN, *Secretary.*

[FR Doc.71-13640 Filed 9-15-71;8:49 am]

OFFICE OF EMERGENCY PREPAREDNESS

NEW JERSEY

Notice of Major Disaster and Related Determinations

Pursuant to the authority vested in me by the President under Executive Order 11575 of December 31, 1970; and by virtue of the Act of December 31, 1970, entitled "Disaster Relief Act of 1970" (84 Stat. 1744); notice is hereby given that on September 4, 1971, the President declared a major disaster as follows:

I have determined that the damages in certain areas of the State of New Jersey from heavy rains and flooding, beginning about August 27, 1971, are of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 91-606. I therefore declare that such a major disaster exists in the State of New Jersey. You are to determine the specific areas within the State eligible for Federal assistance under this declaration.

Notice is hereby given that pursuant to the authority vested in me by the President under Executive Order 11575 to administer the Disaster Relief Act

MOU 225-71-8003

**Memorandum of Understanding Between
The Federal Trade Commission
and The Food and Drug Administration**

SUBJECT: MOU with Federal Trade Commission Concerning Exchange of Information (FDA-225-71-8003)

This Memorandum of Understanding updates and replaces:

A. "Working Agreement Between the Federal Trade Commission and the Food and Drug Administration-June 1954."

B. "Liaison Agreement Between the Federal Trade Commission and the Food and Drug Administration-January 23, 1958."

I. Purpose:

A. It is agreed that the common objective of preventing injury and deception of the consumer requires that the statutory authorities and procedures, and the manpower and other resources available to each agency are so employed as to afford maximum protection to the consumer. This means joint planning of coordinated programs, exchange of information and evidence to the extent permitted by law, by the staffs of both agencies in appropriate undertakings, and the careful selection of the procedure of either agency (or simultaneously by both) promising greatest benefits to the public.

B. In order to provide for exchange of complete information so that both agencies will be utilized to the maximum effectiveness in the public interest, each agency will designate a liaison officer to serve as the primary source of contact. These liaison officers will be responsible for currently informing each other of proposed proceedings and of internal developments in areas of joint concern to the extent that such information is not privileged.

II. Designated Liaison Officers

A. Federal Trade Commission

The Assistant to the General Counsel of the Federal Trade Commission

B. Food and Drug Administration

The Associate Commissioner for Compliance of the Food and Drug Administration.

III. In order to facilitate the purposes of this agreement, it is specifically agreed that:

A. With exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdication over all matters regulating the truth or falsity of advertising of foods, drugs (with the exception of prescription drugs) devices, and cosmetics;

B. The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising. In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics;

C. The initiation of proceedings involving the same parties by both agencies shall be restricted to those highly unusual situations where it is clear that the public interest requires two separate proceedings. For the purpose of avoiding duplication of work and to promote uniformity and consistency of action in areas where both agencies have a concern and the actions of one agency may affect proceedings by the other, it is recognized that such liaison activity is required in instances where:

1. The same, or similar claims are found in both labeling and advertising;

2. Written, printed or graphic material may be construed as either advertising or as accompanying labeling or both, depending upon the circumstances of distribution;

3. The article is a drug or device and appears to be misbranded solely because of inadequacy of directions for use appearing in the labeling for conditions for which the article is offered in advertising generally disseminated to the public.

IV. It is further agreed that:

Regulations promulgated under section 5 of the Fair Packaging and Labeling Act by the respective agencies for the commodities for which they have jurisdiction under that Act, shall be as uniform as possible.

V. Meeting to be held:

The respective liaison officers will hold meetings from time to time to discuss matters of concern to each agency and that they will be accompanied by whatever staff they may deem appropriate and necessary.

VI. Period of agreement;

This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice.

Approved and Accepted
for the Federal Trade Commission
Signed by: Miles W. Kirkpatrick
Chairman, Federal Trade Commission
Date: May 14, 1971
By direction of the Commission dated September 9, 1971.
Charles A. Tabin
Secretary

Approved and Accepted
for the Food and Drug Administration
Signed by: Charles C. Edwards, M.D.
Commissioner of Food and Drugs
Date: April 27, 1971

More in Domestic MOUs (/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm)

Exhibit B

IN THE CHANCERY COURT OF HINDS COUNTY, MISSISSIPPI
FIRST JUDICIAL DISTRICT

THE STATE OF MISSISSIPPI,
Ex rel. JIM HOOD, ATTORNEY GENERAL **PLAINTIFF**

VS. **CIVIL ACTION NO. G2014-1207 T/1**

JOHNSON & JOHNSON, ET AL. **DEFENDANTS**

PLAINTIFF'S RESPONSE TO DEFENDANT JOHNSON & JOHNSON CONSUMER COMPANIES, INC. ("JJCC")'S FIRST SET OF INTERROGATORIES

PROPOUNDING PARTY:	Defendant JOHNSON & JOHNSON CONSUMER COMPANIES, INC.
RESPONDING PARTY:	Plaintiff THE STATE OF MISSISSIPPI, Ex rel. JIM HOOD, ATTORNEY GENERAL
SET NO.:	One

Pursuant to Rules 26 and 33 of the Mississippi Rules of Civil Procedure, Plaintiff, the State of Mississippi, ex rel. the Honorable Jim Hood, Attorney General for the State of Mississippi, by and through the undersigned counsel of record, responds to Defendant Johnson & Johnson Consumer Companies, Inc.'s First Set of Interrogatories to the State of Mississippi, subject to the accompanying objections.

GENERAL OBJECTIONS

The State objects to Defendant's Instructions and Definitions to the extent they purport to impose obligations upon the State that are different or greater than those set forth in the Mississippi Rules of Civil Procedure. Defendant JJCC's Interrogatories are substantially overbroad and unduly burdensome to the extent that they seek admissions to legal conclusions in

dispute and are not tailored to reduce and simplify the facts in this controversy. The Interrogatories propounded by Defendant seek responses to information exclusively in the possession and/or control of Defendants.

Defendant JJCC's Interrogatories are also substantially overbroad and unduly burdensome to the extent that they seek information and documents from non-party governmental agencies offices and individuals within the State of Mississippi. The State objects on the basis that any information in the possession of such agencies, offices or individuals of the Mississippi State Government outside the Attorney General's Office are not relevant to any matter at issue in this litigation, and all Interrogatories seeking such information are not reasonably calculated to lead to the discovery of admissible evidence. The State therefore responds to JJCC's Interrogatories based on information and documents that are in the possession, custody and control of the Attorney General's office to the extent such information is not privileged or subject to the work-product doctrine or any other applicable privilege.

Plaintiff has not fully completed its investigation of the facts relating to this action. Discovery is substantially incomplete. These responses are based only upon the information that is presently available to and specifically known by Plaintiff. Further discovery, independent investigation, legal research, and analysis may supply additional facts and add meaning to the known facts, as well as establish entirely new factual conclusions and legal contentions, all of which may lead to the discovery of additional information, thereby resulting in additions to, changes in, and variations from, these responses. Plaintiff will seasonably supplement should additional information or facts become known pursuant to MRCP 26.

The vast majority of JJCC's Interrogatories are also premature and seek to impose duties and requirements on Plaintiff beyond those, or inconsistent with, those imposed by the

Mississippi Rules of Civil Procedure or any other of the legal strictures governing these proceedings.

Defendant's Interrogatories are objectionable because the Interrogatories seek information already in JJCC's possession, custody or control or are in the public domain. Several of the admissions sought are within the control, custody and possession of Defendants and are more easily or equally accessible to JJCC as it is to the Plaintiff.

The State makes no incidental or implied admissions with regard to the contents of these responses. The fact that the State has responded or objected to any Interrogatory or any part thereof should not be taken as an admission that the State accepts or admits the existence of any facts set forth or assumed by the Interrogatory, or that such response or objection constitutes admissible evidence.

The State further objects to each Interrogatory to the extent that it seeks information that is protected from discovery by the attorney-client privilege, work-product doctrine, the State's or any other person's Constitutional, statutory, or common law privacy interests, or any other lawfully recognized privilege or protection (hereinafter "privileged information"). Any inadvertent disclosure of privileged information is not intended and should not be construed to constitute a waiver, either generally or specifically, with respect to such material or the subject matter thereof. If any information within the scope of the attorney client privilege or the attorney work-product doctrine inadvertently is disclosed herein, the State has not done so intentionally and reserve the right to assert these privileges at any time in these proceedings pursuant to the Mississippi Rules of Civil Procedure, and further reserves the right to request the return of all privileged information, including copies of the responses themselves. In addition, all evidentiary objections are reserved and no waiver of any objection is to be implied from these responses. To

the extent that a response might arguably waive an otherwise assertable objection or claim of privilege, such waiver shall be limited to the specific response only and shall not extend to any other discovery.

Despite these objections but subject to them, Plaintiff responds to JJCC's Interrogatories without waiving, but on the contrary, preserving: (a) the right to object, on the ground of competency, privilege, relevance or materiality, or any other proper grounds, to the use of these responses for any purpose, in whole or in part, in any subsequent stage or proceeding in this action; and (b) the right to object on any and all grounds, at any time, to other discovery procedures involving or relating to the subject matter of the discovery to which the State has responded herein.

In responding to these Interrogatories, Plaintiff intends to preserve, and not waive, the following:

(a) all objections to the vagueness, ambiguity, or other infirmity in the form of any of the Interrogatories, and any objections based on the undue burden imposed by them;

(b) all rights to object on any ground to the use of any of the Interrogatories, or their subject matter, in any subsequent proceedings, including the trial of this or any other action;

(c) all rights to object on any ground to any other discovery requests involving or related to the subject matter of these Interrogatories; and

(d) any and all privileges and rights under the applicable Mississippi Rules of Civil Procedure, Local Rules, statutes, or common law.

Plaintiff reserves the right to amend these responses if it learns that inadvertent errors or omissions have been made or additional or more accurate information becomes available.

The foregoing General Objections are hereby incorporated by reference into each and every response below:

INTERROGATORIES

INTERROGATORY NO. 1:

Identify all Persons, other than Your attorneys, who may have factual knowledge of the allegations set forth in the Complaint, including his/her name, business address, business telephone number and a brief summary of the general nature and extent of each Person's knowledge.

RESPONSE TO INTERROGATORY NO. 1:

Objection. The State objects as this Interrogatory is overly broad, unduly burdensome, and invasive of the work-product doctrine. The State further objects to this Interrogatory in that the information is in the Defendant's possession, custody, or control, and is being requested from Defendant in discovery. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

(a) Individuals having factual information relevant to the State's claim and JJCC"s defenses include, but are not limited to, individuals identified in the documents produced by all of the defendants and third parties in the *Berg*, *Chesteen, Fox*, *Hogans, Oules*, and *Ristesundt* cases,

as well as the fact and expert witnesses disclosed, deposed or listed for trial in any of those cases. In addition, any of the scientists involved in any of the scientific studies discussing the association with ovarian cancer with the repeated use of talc on the perineum;

The State also identifies the Defendants to this action: Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc. (hereinafter the "J&J Defendants"), and Valeant Pharmaceuticals International, Inc. and Valeant Pharmaceuticals North America, LLC (hereinafter the "Valeant Defendants"), and their officers, directors, employees, staff, agents, contractors, and third-party distributors who were involved, at any time during the relevant time periods of 1962 to the present, in the marketing, manufacturing, sale, research, distribution, regulatory compliance, and/or quality assurance of any of the subject Talc Products. The names, identities, and titles of these individuals are not readily available to Plaintiff as discovery is ongoing and the Defendant entities have not supplied that information.

The State also identifies the officers, directors, employees, staff, contractors, and third-party distributors of Imerys Talc America, Inc., which at all relevant times supplied the Defendants with the talc to be manufactured into the Talc Products.

The State also identifies and names certain individuals employed by, retained, or associated with VPNA, VPII, J&J, JJCC, and talc manufacturer funded lobbying and/or advocacy organizations, including but not limited to, Dr. Bruce Semple, who was employed by the J&J Defendants; Ralph Larson, former C.E.O. of the Johnson & Johnson entities; Alfred Wehner, a toxicology consultant retained by the talc product manufacturers; Michael Chudkowski, manager of Pre-Clinical Toxicology at JJCC, Inc.; E. Edward Kavanaugh, past President of the CTFA; the current and past Presidents of the CTFA from 1960 to current; and Mark Ellis, past President of Industrial Minerals Association – North America.

(b) Each of these individuals may have knowledge regarding the State's claim arising from the deceptive advertising and misrepresenting the safety of the Talc Products, and may have knowledge regarding the unity of interest and agency relationships that existed between all the Defendants, and knowledge regarding conspiratorial agreements entered into between talc manufacturers, including JJCC.

INTERROGATORY NO. 2:

Identify all Persons, other than Your attorneys, who may have factual knowledge of any defenses asserted by JJCC in this lawsuit, including his/her name, business address, business telephone number and a brief summary of the general nature and extent of each Person's knowledge.

RESPONSE TO INTERROGATORY NO. 2:

Objection. The State objects as this Interrogatory is overly broad, unduly burdensome, and invasive of the work-product doctrine. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available. The interrogatory is also vague as to whether "defenses" refers only to legal defenses, factual defenses, or some other definition. To the extent the Interrogatory refers to legal defenses asserted in JJCC's answer, it improperly seeks a legal opinion.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 1.

INTERROGATORY NO. 3:

Identify all uses of the Talc Products and other talc products related to Your claims in the Complaint that You allege cause or have caused ovarian cancer, and other adverse health effects or events.

RESPONSE TO INTERROGATORY NO. 3:

Objection. The State objects to this Interrogatory as vague to the extent it does not define "uses," "other talc products," "cause" or "other adverse health effects or events." The State further objects to this Interrogatory to the extent it seeks an expert opinion and exceeds the scope of discovery allowed by M.R.C.P. 26.

Subject to and without waiving its objections, the State responds as follows:

The State has alleged that repeated perineal use of the Talc Products, as defined by the scientific studies referenced in the State's Complaint, causes an increased risk of ovarian cancer.

INTERROGATORY NO. 4:

Describe each action taken by the State of Mississippi, before filing the Complaint, to seek a statement and/or opinion from any regulatory authority including, but not limited to, the Food and Drug Administration, regarding either the Talc Products, or the health effects of cosmetic talc use, with regard to the following allegation in the Complaint: Paragraph 5, that there is "a dangerous and potentially lethal health risk associated with the use of the[] Talc Products."

RESPONSE TO INTERROGATORY NO. 4:

Objection. The State objects to this Interrogatory as vague and overly broad in that it does not specify or define what constitutes seeking "statement" and "opinion"; and fails to distinguish

between "statement" and "opinion"; the Interrogatory does not define "regulatory authority" leaving the term open for potentially limitless interpretation and could include regulatory agencies on the national, state, and local level, nor does it define "health effects." Further, the Interrogatory is improper to the extent it seeks privileged information or information protected by the work-product doctrine.

Subject to and without waiving its objections, the State responds as follows: the State investigated the publicly available statements and opinions regarding the cosmetic use of talc issued by the FDA before filing the Complaint. The State determined that the FDA had issued a statement on the safety of the cosmetic use of talc, which may be accessed at http://www.fda.gov/cosmetics/productsingredients/ingredients/ucm293184.htm. The FDA statement indicates, among other things, that: "Cosmetic companies have a legal responsibility for the safety and labeling of their products and ingredients, but the law does not require them to share their safety information with FDA." The State further investigated publicly available information to determine what action, if any, JJCC and the other Defendants had taken to seek regulatory guidance or oversight from the FDA or any other regulatory authority regarding the cosmetic use of talc and found no indication Defendants had taken any action at all.

INTERROGATORY NO. 5:

Identify each person acting on behalf of the State of Mississippi, before filing the Complaint, who sought a statement and/or opinion from any regulatory authority including, but not limited to, the Food and Drug Administration regarding either the Talc Products, or the health effects of cosmetic talc use, regarding the following allegations in the Complaint: Paragraph 4, that JJCC used "deceptive and false labeling and marketing of the Talc Products in violation of Miss. Code Ann. § 75-24-5," and Paragraph 5, that JJCC "engaged in

misrepresentations and omissions in connection with the labeling, advertisements, promotion, marketing, and sale of their Talc Products," and provide a summary of all such communications, including the dates of such communications.

RESPONSE TO INTERROGATORY NO. 5:

Objection. The State objects to this Interrogatory as vague and overly broad in that it does not specify or define "health effects" or what constitutes seeking a "statement" or "opinion" and fails to distinguish between "statement" and "opinion;" the Interrogatory does not define "regulatory authority" leaving the term open for potentially limitless interpretation and could include regulatory agencies on the national, state, and local level. Further, the Interrogatory is improper to the extent it seeks privileged information or information protected by the work-product doctrine.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 4.

INTERROGATORY NO. 6:

Identify each specific danger, adverse health effect, or other event including, but not limited to, ovarian cancer related to the Talc Products about which You allege JJCC should have warned or informed its customers and/or the public.

RESPONSE TO INTERROGATORY NO. 6:

Objection. The State objects to this Interrogatory as vague to the extent it does not define "danger," and "adverse health effects or other event." The State further objects to this Interrogatory to the extent it seeks an expert opinion and exceeds the scope of discovery allowed by M.R.C.P. 26. The State further objects to this contention interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this

contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

The J&J Defendants should have warned the public and specifically the citizens and residents of Mississippi not to use its Talc Products perineally or in the alternative, at a minimum, should have informed the public that perineal use of talc-containing products causes an increased risk of ovarian cancer and causes cancer in some women. The J&J Defendants have never warned or informed any Mississippi citizens and residents, whether through the product labeling, marketing or advertising, that numerous scientific studies have shown a statistically significant increased risk of ovarian cancer with the repeated use of the Talc Products in the female genital or perineal area. Through failing to warn or convey this information regarding the studies associating the use of talc powders and ovarian cancer, the J&J Defendants increased the risk that numerous Mississippi citizens and residents may develop ovarian cancer, damaging the health and welfare of State residents, the public health interests of the State at large, and taxing the economic resources of the citizenry and the State through increased private and public health care spending.

INTERROGATORY NO. 7:

For each specific danger or adverse health effect or event identified in Interrogatory No. 6, describe the specific warning or instruction You allege JJCC should have provided to its customers and/or the public and the date You allege such warning or instruction should have been provided.

RESPONSE TO INTERROGATORY NO. 7:

Objection. The State objects to this Interrogatory as vague to the extent it does not define "danger," and "adverse health effects" and "event." The State objects to this Interrogatory to the extent it seeks an expert opinion and exceeds the scope of discovery allowed by M.R.C.P. 26. The State objects to this Interrogatory—which constitutes a contention interrogatory—as premature, as discovery has just began in this matter and pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Discovery is still undergoing. Plaintiff will supplement this response as it becomes available.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory 6.

INTERROGATORY NO. 8:

Identify all defects that You allege are associated with the Talc Products and, for each such defect claimed, state precisely all facts and information upon which You rely to support the contention, identify each person, firm or corporation who has knowledge of such facts or information, including their business address and phone number, and identify each document relating to or containing such facts or information, and set forth specifically what You contend the warning on the Talc Products should have stated.

RESPONSE TO INTERROGATORY NO. 8:

Objection. The State objects to this Interrogatory—which constitutes a contention interrogatory—as premature, as discovery has just began in this matter and pursuant to M.R.C.P.

33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. The State objects to this Interrogatory to the extent it seeks an expert opinion and exceeds the scope of discovery allowed by M.R.C.P. 26. Discovery is still undergoing. Plaintiff will supplement this response as appropriate if additional information becomes available. The State objects to this Interrogatory as overbroad to the extent it seeks legal conclusions or opinions. The Interrogatory is also vague as to whether "defects" refers only to legal claims, factual claims, or some other definition.

Subject to and without waiving its objections, the State responds as follows:

The State has brought a single legal claim against JJCC for violating the Mississippi Consumer Protection Act, Miss, Code Ann. §§ 75-24-5(1) and (2). The State has alleged that JJCC, along with the other Defendants named, engaged in unfair methods of competition and unfair and deceptive trade practices in or affecting commerce:

a. "in the course of trade or commerce, Defendants misrepresented their goods as having uses and/or benefits that they do not have in violation of Miss. Code Ann. § 75-24-5(2)(e);" [Complaint ¶ 96(a)].

The J&J Defendants have marketed Talc Products and continue to market Johnson's Baby Powder for cosmetic use – as daily use powder safe for human use that is intended to maintain freshness and cleanliness, to eliminate friction on the skin, and to absorb unwanted excess moisture for women. Nowhere have the Defendants provided available safety information regarding the increased risk of ovarian cancer linked to the perineal use of the Defendants' Talc Products. This potentially lethal effect of talc makes it wholly unsuitable for perineal use.

JJCC and the other Defendants have advertised and marketed the Talc Products

as safe for perineal use by women. Historically, Johnson's Baby Powder® was marketed as a symbol of freshness, cleanliness, and purity. During the time in question, Defendants advertised and marketed their product as the beacon of "freshness" and "comfort," eliminating friction on the skin, absorbing "excess wetness" helping keep skin feeling dry and comfortable, and "clinically proven gentle and mild." Defendants persuaded women through advertisements to dust themselves with their product to mask odors. The bottle of Johnson's Baby Powder® specifically targets women by stating, "For you, use every day to help feel soft, fresh, and comfortable."

Prior to 2012, the J&J Defendants advertised and marketed "Shower to Shower" with slogans and statements, including but not limited to, "A sprinkle a day keeps odor away," and through advertisements including, but not limited to: "Your body perspires in more places than just under your arms. Use SHOWER to SHOWER to feel, dry, fresh and comfortable throughout the day" and "SHOWER to SHOWER can be used all over your body." These slogans directly suggested that women should apply Shower to Shower® products in way that is unsuitable for safe use. The J&J Defendants' advertising, marketing, and labeling of Shower to Shower® products intentionally made perineal use an intended and foreseeable use of the Talc Products.

No marketing, labeling, packaging, or advertisement of the Talc Products informed consumers of the available safety information regarding the increased risk of ovarian cancer linked to the perineal use of the products. The J&J Defendants marketed the Talc Products as safe for cosmetic use, including perineal use. The J&J Defendants and their successors, the Valeant Defendants, made these representations and suggested that women use the product in an unsafe manner while the companies knew of 30 years of studies demonstrating that women use

of talc-based powder in the genital area had been associated with a significant increased risk of ovarian cancer. The J&J Defendants were informed of this increased risk by their talc suppliers, consultants, employees, and through industry and governmental agencies.

JJCC never informed Mississippi citizens and residents of the safety issues associated with perineal use of its Talc Product.

b. "[I]n the course of trade or commerce, Defendants misrepresented their goods as having qualities and/or standards that they did not have in violation of Miss. Code Ann. § 75-24-5(2)(g)"; [Complaint ¶ 96(b)]

The J&J Defendants have marketed and continue to market their Talc Products for cosmetic use – as daily use powder safe for human use that is intended to maintain freshness and cleanliness, eliminate friction on the skin, and to absorb unwanted excess moisture for women. Nowhere have the Defendants informed consumers of the available safety information regarding the increased risk of ovarian cancer linked to the perineal use of the Defendants' Talc Products. In so doing, in addition to misrepresenting the uses and/or benefits of its product, JJCC has misrepresented the safety of the use of its product as well.

c. "Defendants actively promoted, advertised and marketed their products by disseminating misrepresentations and omissions to Mississippi consumers, focusing on certain minority communities;" [Complaint ¶ 96(c)]

In an August 5, 1992 document entitled "Johnson's Baby Powder...Major Opportunities," in an effort to "grow the franchise," the Johnson & Johnson entities implemented a strategy of targeting African-American and Hispanic women since its internal studies showed these two ethnicities used Baby Powder® at higher rates than other ethnicities of women.

In the same document, the J&J Defendants, including JJCC, acknowledged that: "Negative publicity from health community on talc continues . . . cancer linkage." The racially targeted strategy implemented by the J&J Defendants, including JJCC, and the other Defendants

has and continues to disproportionately affect the citizens of Mississippi since approximately forty (40%) of Mississippi's population is comprised of African-American and Hispanic individuals.

JJCC failed to pass on to its consumers, including Mississippi residents, a warning on the Material Safety Data Sheets its talc supplier Imerys provided to cosmetic manufacturers to which it supplied talc, classifying talc as "very toxic," and "cancer causing." By failing to pass this information given to JJCC by its own supplier of raw talc on to consumers, JJCC continued to misrepresent and withhold knowledge regarding the unsafe use of its products.

At all relevant times, JJCC expressly and impliedly represented to these minority communities and the public at large that its Talc Products were safe for all uses.

INTERROGATORY NO. 9:

Describe each element of the Talc Product labeling referenced in Paragraph 5 of the Complaint that You allege violated Miss. Code Ann. § 75-24-5, including an identification of the provision of § 75-24-5 You contend was violated by the labeling.

RESPONSE TO INTERROGATORY NO. 9:

Objection. The State objects to the extent this Interrogatory calls for disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of the State pursuant to M.R.C.P 26. Discovery is still undergoing. Plaintiff will supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 8.

INTERROGATORY NO. 10:

Describe the advertisements or marketing referenced in Paragraph 5 of the Complaint that

You allege violated Miss. Code Ann. § 75-24-5, including the date on which the information was disseminated in Mississippi, including an identification of the provision of § 75-24-5 You contend was violated by the advertisements or marketing.

RESPONSE TO INTERROGATORY NO. 10:

Objection. The State objects to the extent this Interrogatory calls for disclosure of the mental impressions, conclusions, opinions, or legal theories of an attorney or other representative of the State pursuant to M.R.C.P 26. Discovery is still undergoing. Plaintiff will supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 8.

INTERROGATORY NO. 11:

Describe all facts known to You that support Your allegation in Paragraph 4 of the Complaint that the labeling and marketing of the Talc Products was "deceptive and false," including an identification of each person, firm, or corporation, including their business address and phone number, who has knowledge of such facts or information and an identification of each document relating to or containing such facts or information.

RESPONSE TO INTERROGATORY NO. 11:

Objection. The State objects to this Interrogatory—which constitutes a contention interrogatory—as premature, as discovery has just began in this matter and pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Discovery is still undergoing. Plaintiff will supplement this response as appropriate if additional information becomes available. The State further objects to this Interrogatory as compound and

thus violative of MRCP 33(a).

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 8.

INTERROGATORY NO. 12:

Identify the date and circumstances under which You first became aware that the perineal use of the Talc Products and/or other talc-based personal care products allegedly caused adverse health effects or events including, but not limited to, ovarian cancer.

RESPONSE TO INTERROGATORY NO. 12:

Objection. The State objects to this Interrogatory as vague and overly broad to the extent it does not define "other talc-based personal care products." The State further objects to this Interrogatory to the extent it seeks information protected by the attorney-client privilege or work-product doctrine.

Subject to and without waiving its objections, the State became aware of the medical literature demonstrating a statistically significantly increased risk of ovarian cancer with the perineal use of the Talc Products on or about September 2013.

INTERROGATORY NO. 13:

Identify with specificity all facts known to You that support the Cause of Action that You have asserted in the Complaint against JJCC [(as distinguished from Defendant Johnson & Johnson Inc. ("J&J")] including, but not limited to, any acts or omissions on the part of JJCC.

RESPONSE TO INTERROGATORY NO. 13:

Objection. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial

documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available. The State objects to this Interrogatory to the extent it calls for an expert opinion and it seeks information that is attorney-client privileged or subject to the work-product doctrine.

Subject to and without waiving its objections, the State responds as follows:

The State's facts are derived from the J&J Defendants' packaging, labeling, advertisements, websites, the J&J Defendants' annual reports, SEC disclosures, third-party retailers websites, and scientific studies and publications, letters, and memoranda from scientific organizations and cancer advocacy groups linking the use of Talc Products to ovarian cancer from the 1960's to current. These studies, letters, and memoranda include but are not limited to: Egli GE, Newton M. "The transport of carbon particles in the human female reproductive tract." *Fertility Sterility* 1961; 12:151-155(showing that talc like particles can translocate from the exterior genital area to ovaries in women); Cralley LJ, Key MM, Groth DH, Lainhart WS, Ligo, RM. "Fibrous and mineral content of cosmetic talcum products." *Am. Industrial Hygiene Assoc. J.* 1968; 29:350-354 (cautioning that the asbestos-like fibers in talc may cause unsuspected problems if used without precaution); Rohl AN, Langer AM, Selifoff IJ, Tordini A, Klimentidis R, Bowes DR, Skinner DL. "Consumer talcums and powders: mineral and chemical characterization." *J. Toxicol. Environ. Health* 1976; 2:255-284 (finding the presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc. . .We also recommend that evaluation be made to determine the possible health hazards

associated with the use of these products."); Cramer, D.W.; Welch, W.R.; Scully, R.E.; Wojciechowski, C.A. "Ovarian cancer and talc: a case control study." *Cancer* 1982; 50: 372-376; a 1982 study conducted by Dr. Daniel Cramer of Bringham and Women's Hospital. Cramer, D.W.; Welch, W.R.; Scully, R.E.; Wojciechowski, C.A., "Ovarian cancer and talc: a case control study." Cancer 1982; 50: 372-376, 1982; Hartge, P; Hoover, R.; Lesher, L.P.; McGowan, L. "Talc and ovarian cancer." *JAMA,* 1983; 250(14): 1844; Hartge P, Hoover R, Lesher LP, McGowan L. "Talc and ovarian cancer." Letter JAMA 1983; 250: 1844; Whittemore AS, Wu ML, Paftenbarger, RS, Sarles DL, Kampert JB, Grosser S, Jung DEL, Ballon S, Hendrickson M. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures talcum powder, tobacco, alcohol, and coffee." *Am. J. Epidemiol.* 1988; 1128: 1228-1240; Whittemore, A.S.; Wu, M.L.; Paffenbarger, R.S., Jr.; et al. "Personal and environmental characteristics related to epithelial ovarian cancer. II. Exposures to talcum powder, tobacco, alcohol, and coffee." *Am. J. Epidemiol.* 1988; 128 (6): 1228-1240; Booth, M.; Beral, V.; Smith, P.; "Risk factors for ovarian cancer: a case-control study." *Br. J. Cancer.* 1989; 60 (4): 592-598; Harlow, B.L.; Weiss, N.S. Harlow, B.L.; Cramer, D.W.; Bell, D.A.; Welch, W.R. "Perineal exposure to talc and ovarian cancer risk." *Obstet. Gynecol.* 1992; 45 (1): 20-25; "A case-control study of borderline ovarian tumors: the influence of perineal exposure to talc." *Am. J. Epidemiol.* 1989; 130 (2): 390-394; Rosenblatt KA, Szklo M, Rosenshein NB. " Mineral fiber exposure and the development of ovarian cancer." *Gynecol. Oncol.* 1992; 45:20-25; Harlow BL, Cramer DW, Bell DA, Welch WR. "Perineal exposure to talc and ovarian cancer risk." *Obstet. Gynecol.* 1992; 80:: 19-26; Yong Chen; Pao-Chen Wu; Jeng-He Lang; Wen-Jun Ge; Hartge, P.; and Brinton, L.A. "Risk Factors for Epithelial Ovarian Cancer in Beijing, China." *Int. J. Epidemiol.* 1992; (21 (1): 23-29; National Toxicology

Program. "Toxicology and carcinogenesis studies of talc (CAS No 14807-96-6) in F344/N rats and B6C3F 1 mice (Inhalation studies)." *Technical Report Series No. 421,* September 1993; Purdie, D.; Green, A.; Bain, C.; et al. "Reproductive and other factors and risk of epithelial ovarian cancer: an Australian case-control study. Survey of Women's Health Study Group." *Int. J. Cancer.* 1995; 62 (6): 678-684; November 10, 1994 letter from the Cancer Prevention Coalition to Ralph Larson, C.E.O. to Johnson & Johnson; Gross, A.J.; Berg, P.H. "A meta-analytical approach examining the potential relationship between talc exposure and ovarian cancer." *J. Expo. Anal. Environ. Epidemiol.* 1995; 5 (2): 181-195; McCullough, Marie, "Women's health concerns prompt condom makers to stop using talc." *Jersey Journal (City Edition)*, April 17, 1996; Cook, L.S.; Kamb, M.L.; Weiss, N.S. "Perineal powder exposure and the risk of ovarian cancer." *Am. J. Epidemiol.* 1997; 145: 459-465; Shushan, A.; Paltiel, O.; Iscovich, J.; Elchalal, U.; Peretz, T.; Schenker, J.G., "Human menopausal gonadotropin and the risk of epithelial ovarian cancer." *Fertil. Steril.* 1995; 65 (1): 13-18; Chang, S.; Risch, H.A. "Perineal talc exposure and risk of ovarian carcinoma." *Cancer.* 1997; 79 (12): 2396-2401; September 17, 1997, letter from Alfred Wehner, toxicology consultant retained by Johnson and Johnson Consumer Companies, to Michael Chudkowski, manager of Pre-Clinical toxicology at JJCC stating that on three separate occasions the Talc Interested Party Task Force ("TIPTF") of the CTFA, had released false information to the public about the safety of talc; Godard, B. et al., "Risk factors for familial and sporadic ovarian cancer among French Canadians: a case-control study." *Am. J. Obstet. Gynecol.* 1998; 179 (2): 403-410; Ness, R.B.; Grisso, J.A.; Cottreau, C.; et al. "Factors related to inflammation of the ovarian epithelium and risk of ovarian cancer. *Epidemiology.* 2000; 11 (2): 111-117; Cramer, D.W.; Liberman, R.F.; Titus-Ernstoff, L.; et al. "Genital talc exposure and risk of ovarian cancer." *Int. J. Cancer.* 1999; 81 (3): 351-356; Gertig,

D.M.; Hunter, D.J.; Cramer, D.W.; Coditz, G.A.; Speizer, F.E.; Willett, W.C.; Hankinson, S.E. "Prospective study of talc use and ovarian cancer." *J. Natl. Cancer Inst.;* 2000; 92: 249-252; Huncharek, M.; Geschwind, J.F.; Kupelnick, B. "Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: a meta-analysis of 11,933 subjects from sixteen observational studies." *Anticancer Res.* 2003; 23: 1955-60; Mills, P.K.; Riordan, D.G.; Cress, R.D.; Young H.A. "Perineal talc exposure and epithelial ovarian cancer risk in the Central Valley of California." *Int. J. Cancer.* 2004; 112:458-64; February 26, 2002 internal memorandum within Imerys, the supplier of talc to the Johnson and other Defendants, entitled "NTP Talc Review Status," "Special Litigation Issues & Problems;" 2002 letter from E. Edward Kavanaugh, President of CTFA, to Dr. Kenneth Olden, Direct of the National Toxicology Program and National Institute of Environmental Health Sciences, U.S. Department of Human Services, requesting that the NTP not list cosmetic talc as a carcinogen in the 10th Report on Carcinogens Report, 2006 to current warning printed on the Material Safety Data Sheets, Imerys provided to the cosmetic companies it supplied talc to, classifying talc as "very toxic," and "cancer causing;" M. Steven Piver, et al. "Myths & Facts about ovarian cancer: What you need to know." *CMP Medica.* 2007 5th Ed; Buz'Zard A.R.; Lau, B.H., "Pycnogenol reduces talc-induced neoplastic transformation in human ovarian cell cultures." *Phytother. Res.* 2007; 21 (6): 579-586; May 2008 petition by the CPC, joined by physicians and chairs of public health and medical associations, "seeking a cancer warning on cosmetic talc products," and the scientific studies cited therein; Gates, M.A.; Shelley, S.; Tworoger, S.S.; Terry, K.L.; Titus-Ernstoff, L.; *et al.* "Talc Use, Variants of the GSTM1, GSTT1, and NAT2 Genes, and Risk of Epithelial Ovarian Cancer." *Cancer Epidemiology, Biomarkers & Prev.* 2008; 17 (9): 2436-2444; Chustecka, Zosia; Lie, Desiree, "Talc Use in Genital Area Linked to Increased Risk for Ovarian

Cancer," *Medscape Medical News,* 2008; Merritt, M.A.; Green, A.C.; Nagle, C.M.; Webb, P.M., "Talcum powder, chronic pelvic inflammation and NSAIDs in relation to risk of epithelial ovarian cancer." *Int. J. Cancer.,* 2008; 122 (1):170-176; Wu, A.H.; Pearce, C.L.; Tseng, C.C.; Templeman, C.; Pike, M.C., "Markers of inflammation and risk of ovarian cancer in Los Angeles County," *Int. J. Cancer.* 2009; 124 (6): 1409-1415; Rosenblatt, K.A.; Weiss, N.S.; Cushing-Haugen, K.L.; Wicklund, K.G.; Rossing, M.A., "Genital powder exposure and the risk of epithelial ovarian cancer," *Cancer Causes Control.* 2011; 22(5): 737-742; Terry, K.L.; Karageorgi, S.; Svetsov, Y.B.; Merritt, M.A.; Lurie, G.; et al., "Genital Powder Use and Risk of Ovarian Cancer: A Pooled Analysis of 8,525 Cases and 9,859 Controls," *Cancer Prevention Research* 2013; 6: 811-821); and "Association between Body Powder Use and Ovarian Cancer: the African American Cancer Epidemiology Study (AACES)," *Cancer Epidemiology, Biomarkers & Prevention* 2016, 25, Schildkraut, J.M., et al.

INTERROGATORY NO. 14:

Identify all persons having facts, and provide a brief summary of facts known to each person that support Your contention in Paragraph 17 of the Complaint that JJCC and Defendant Valeant Pharmaceuticals "acted in concert and/or aided and abetted each other and conspired to engage in the common course of misconduct alleged [in the Complaint]."

RESPONSE TO INTERROGATORY NO. 14:

Objection. The State objects to this Interrogatory—which constitutes a contention interrogatory—as premature, as discovery has just began in this matter and pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the

Interrogatory with the full details sought is largely within Defendants' own possession. The State further objects to this Interrogatory as compound and thus violative of the scope of MRCP 33(a). The State further objects on the basis that Interrogatory directly seeks disclosure of "mental impressions, conclusions, opinions, or legal theories" of counsel, which are absolutely protected from discovery by the work-product privilege. MRCP 26(b)(3); *Hewes v. Langston*, 853 So.2d 1237, 1245-46 (Miss. 2003). Discovery is still undergoing. Plaintiff will supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

Plaintiff responds that the J&J Defendants control the sale of their products, and the decisions regarding the manufacture, distribution and sale, as well as the packaging, messaging and marketing of the Talc Products that give rise to this litigation. Further, the J&J Defendants had ownership interests and may have ongoing liabilities arising from the Shower to Shower product along with the Valeant defendants.

On September 17, 1997, Alfred Wehner, a toxicology consultant retained by Defendants, wrote a letter to Michael Chudkowski, manager of Pre-Clinical Toxicology at JJCC, Inc., stating that on three separate occasions the Talc Interested Party Task Force ("TIPTF") of the CTFA, which included Defendants, had released false information to the public about the safety of talc. Specifically addressing a November 17, 1994 statement released by the Cosmetics, Toiletry, and Fragrance Association ("CTFA"), Dr. Wehner said the following:

> The response statement dated November 17, 1994, is just as bad. The second sentence in the third paragraph reads: "The workshop concluded that, although some of these studies suggested a weak association might exist, when taken together the results of the studies are insufficient to demonstrate any real association." This statement is also inaccurate, to phrase it euphemistically. At that time there had been about 9 studies (more by now) published in the open literature that did show a statistically significant association

> between hygienic talc use and ovarian cancer. Anybody who denies this risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary.
>
> The workshop did not conclude that "the results of the studies are insufficient to demonstrate any real association." As pointed out above, a "real" statistically significant association has been undeniably established independently by several investigators, which without doubt will be readily attested to by a number of reputable scientists/clinicians, including Bernard Harlow, Debra Novotny, Candace Sue Kasper Debra Heller, and others.

On February 26, 2002, Imerys, which admittedly supplies all of the talc to Defendants for their Talc Products, wrote in its internal memorandum entitled "NTP Talc Review Status," "Specific Litigation Issues & Problems" the following:

> Listing of "talc not containing asbestos fibers" could be potentially devastating from a product liability perspective. [Plaintiff's attorney: "So Mr. Zazenski, please tell the Court when Luzenac [Imerys] first learned that talc was possibly associated with ovarian cancer?" "When did you first start warning consumers that this association was possible and under study." "Did you not feel a moral and ethical obligation to inform women that the hygienic use of talc may increase their risk for ovarian cancer, or were the profits you were making from mining and selling this potentially dangerous, life-threatening product more important than protecting the health and welfare of the 'women and children in our society?'" Etc. etc. etc.]

[Complaint ¶ 38].

In 2002, E. Edward Kavanaugh, the President of the CTFA, wrote a letter to Dr. Kenneth Olden, Director of the National Toxicology Program ("NTP") and National Institute of Environmental Health Sciences, U.S. Department of Health and Human Services, in an attempt to stop the NTP from listing cosmetic talc as a carcinogen in the upcoming 10th Report on Carcinogens (RoC) Report. JJCC and J&J as separate entities and as the predecessors in interest to the Johnson & Johnson entities, have been long-standing, active

members and donors of the CTFA.

On July 12, 2006, Eric Turner, Vice-President of Health, Safety and Environment of Luzenac America, Inc. (Imerys), wrote a letter to Mark Ellis, President of Industrial Minerals Association – North America explaining why the "talc interested parties," were foregoing further funding on a talc study called the "Mossman Study."

INTERROGATORY NO. 15:

Identify each Person You will call as an expert witness at the trial of this case, and for each Person, state that person's business address, and business telephone number, the profession or occupation and the field in which she/he is allegedly an expert; the subject matter in which the expert is expected to testify; the substance of the facts and opinions about which the expert is expected to testify; and a summary of the grounds for each opinion.

RESPONSE TO INTERROGATORY NO. 15:

The State objects to this Interrogatory in that it seeks premature expert disclosures. *See Robert v. Colson*, 729 So. 2d 1243, 1246 (Miss. 1999). No decision has been made concerning any experts which may be relied upon. *See id.* The State will disclose the identities of each expert witness the State intends to call in timely fashion pursuant to the MRCP 26(b)(4)(*a*)(i). The State will provide information on which each expert is expected to testify to the extent required by the Mississippi Rules of Civil Procedure. Plaintiff will produce this information after discovery of the facts has concluded and the expert witnesses have had an opportunity to review the relevant material, summary of the facts and use such and other methods to form an opinion as required.

INTERROGATORY NO. 16:

Identify all persons having facts, and provide a brief summary of facts known to each

person, that support the allegations in Paragraph 5 and 9 of the Complaint that JJCC "intentionally" and "specifically targeted minority communities."

RESPONSE TO INTERROGATORY NO. 16:

Objection. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 1 and 8.

INTERROGATORY NO. 17:

For each occurrence in the Complaint of the phrases "relevant time period," "various times mentioned," "various times relevant," "the time in question," and "all time periods relevant," including in Paragraphs 12, 16, 17, 18, 26, 31 and 32, identify the specific month and year to which You refer.

RESPONSE TO INTERROGATORY NO. 17:

Objection. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full

details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available. The State further objects to this Interrogatory as compound, unduly broad and burdensome, and thus violative of the scope of MRCP 33(a).

Subject to and without waiving its objections, the State responds as follows:

The "time in question" referred to within the Complaint in Paragraphs 31-32, refers to all time during which the Talc Manufacturers failed to warn about the link between the use of talc products and ovarian cancer and continued to market, advertise, promote, and sell the products, beginning in approximately 1961 and continuing through current.

INTERROGATORY NO. 18:

Identify all persons having facts, and provide a brief summary of facts known to each person, that support Your contention that JJCC had notice of the allegedly harmful effects of the Talc Products.

RESPONSE TO INTERROGATORY NO. 18:

Objection. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 1 and 8.

INTERROGATORY NO. 19:

Identify any and all federal or Mississippi state statutes, rules, or regulations with which You claim JJCC has not complied regarding the labeling, marketing, or sale of the Talc Products.

RESPONSE TO INTERROGATORY NO. 19:

The State objects to this Interrogatory as overbroad to the extent it seeks legal conclusions or opinions about which laws, regulations, and rules govern the design, production, sale, warnings, labeling and marketing of JJCC's Talc Products. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available.

Subject to and without waiving its objections, the State responds as follows:

In the Complaint, the State claims that JJCC has violated and continues to violate Miss. Code Ann. §§ 75-24-5(1) and (2).

INTERROGATORY NO. 20:

Identify all manufacturing and/or design defects that You allege are contained in the Talc Products.

RESPONSE TO INTERROGATORY NO. 20:

Objection. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this

contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available. The State objects to this Interrogatory as overbroad to the extent it seeks legal conclusions or opinions. The Interrogatory is also vague as to whether "defects" refers only to legal claims, factual claims, or some other definition.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory No. 8.

INTERROGATORY NO. 21:

Identify all persons acting on Your behalf who have communicated with any and all federal and state governmental agencies, and private entities, regarding the allegation in the Complaint that the perineal use of the Talc Products or other talc-based personal care products causes adverse health effects or events including, but not limited to, all communications in Your pre-suit investigation, and provide a summary of the communication, including the date of any such communication.

RESPONSE TO INTERROGATORY NO. 21:

Objection. The State objects to this Interrogatory as vague and overly broad in that it does not specify or define what constitutes seeking guidance or seeking oversight and fails to distinguish between guidance and oversight; the interrogatory does not define "regulatory authority" leaving the term open for potentially limitless interpretation and could include regulatory agencies on the national, state, and local level. Further, the Interrogatory is improper

to the extent it seeks privileged information or information protected by the work-product doctrine.

Subject to and without waiving its objections, the State responds as follows:

Please see the State's response to Interrogatory Nos. 4 and 5.

INTERROGATORY NO. 22:

Describe in detail each category of damages for which the State seeks recovery from JJCC, including the amount of damages, the methodology used to calculate or derive that amount, and all facts or Documents upon which the State relies to support its claims as to the nature and extent of each category of damages.

RESPONSE TO INTERROGATORY NO. 22:

Objection. The State objects to this Interrogatory to the extent it seeks an expert opinion. The State further objects to this contention Interrogatory as premature since discovery is still underway in this matter. Pursuant to M.R.C.P. 33(c), responding to this contention interrogatory should be deferred until the end of the discovery period when substantial documentary or testimonial discovery has been completed. Further, the State objects to this Interrogatory in that the information required to answer the Interrogatory with the full details sought is largely within Defendants' own possession. Plaintiff will seasonably supplement this response as appropriate if additional information becomes available. The State further objects to this Interrogatory as compound, overly broad, and burdensome, and thus violative of the scope of MRCP 33(a) and exceeds the scope of discovery allowed by M.R.C.P. 26. The State further objects on the basis that Interrogatory directly seeks disclosure of "mental impressions, conclusions, opinions, or legal theories" of counsel, which are absolutely protected from discovery by the work-product privilege. MRCP 26(b)(3); *Hewes v. Langston*, 853 So.2d 1237, 1245-46 (Miss. 2003). The

State further objects to this Interrogatory in that it seeks information in the Defendant's possession, custody, or control and is being requested by Defendant in discovery.

Subject to and without waiving its objections, the State responds as follows:

The State seeks recovery from JJCC for:

1. An award of actual damages to the State in such amount as is later proven at trial, together with prejudgment interest;

2. Punitive damages, in such amount as is later proven at trial.

3. An injunction requiring Defendants to warn of the hazards associated with the use of the Talc Products, to remove all products that fail to warn of the hazards associated with the product, and to prevent the continued violation of the Mississippi Consumer Protection Act;

4. Disgorgement of ill-gotten revenues derived from the sale of Talc Products to Mississippi Residents in an amount determined by an order pursuant to Miss. Code Ann. § 75-24-9 and § 75-24-11 requiring that Defendants submit to an accounting to determine the amount of improperly obtained revenue that was paid to JJCC for sale of their dangerous and defective Talc Products as a result of their unfair and deceptive trade practices, acts, and omissions.

5. A civil penalty of up to but not to exceed Ten Thousand Dollars ($10,000.00) for each and every violation of the Mississippi Consumer Protection Act, Miss. Code Ann. § 75-24-5, the number of violations to be determined after the completion of discovery.

6. Attorneys' fees, investigative costs and other costs of this action, in an amount to be determined by Order of the Court.

INTERROGATORY NO. 23:

Identify all manufacturers or sellers of talc-based products whose products contain a warning with regard to ovarian cancer or a higher risk thereof through the perineal use of said

INTERROGATORY NO. 23:

Identify all manufacturers or sellers of talc-based products whose products contain a warning with regard to ovarian cancer or a higher risk thereof through the perineal use of said products.

RESPONSE TO INTERROGATORY NO. 23:

Objection. The State objects to this Interrogatory to the extent it seeks information that is irrelevant, immaterial, unnecessary, or unrelated to a claim or defense in this case. The State further objects to this Interrogatory to the extent it seeks information from third parties.

Subject to and without waiving its objections, the State responds that it is aware that the manufacturer of the talc used in the Talc Products, Imerys Talc America, Inc., includes a warning on its Material Safety Data Sheet, warning users of the increased risk of ovarian cancer with the perineal use of talc.

RESPECTFULLY SUBMITTED, this the 5th day of October, 2016.

THE STATE OF MISSISSIPPI, *Ex rel.*
JIM HOOD, ATTORNEY GENERAL

By: _____

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CERTIFICATE OF SERVICE

I hereby certify that on this day I served the foregoing *Plaintiff's Response to Defendant Johnson & Johnson Consumer Companies, Inc. ("JJCC")'s First Set of Interrogatories* by electronic mail and U.S. Mail sent to the following:

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So certified this the 5th day of October, 2016.

Jacqueline H. Ray, MSB #100169

IN THE CHANCERY COURT OF HINDS COUNTY, MISSISSIPPI
FIRST JUDICIAL DISTRICT

THE STATE OF MISSISSIPPI,
Ex rel. JIM HOOD, ATTORNEY GENERAL **PLAINTIFF**

VS. **CIVIL ACTION NO. G2014-1207 T/1**

JOHNSON & JOHNSON, ET AL. **DEFENDANTS**

VERIFICATION

STATE OF MISSISSIPPI
COUNTY OF HINDS

PERSONALLY appeared before me, the undersigned authority in and for the aforesaid jurisdiction, the within named **Jacqueline H. Ray,** who being by me first duly sworn, states on oath that the matters, facts and things alleged, contained and set forth in the above and foregoing *Plaintiff's Response to Defendant Johnson & Johnson Consumer Companies, Inc. ("JJCC")'s First Set of Interrogatories* are true and correct as therein stated to the best of her knowledge, information and belief.

THIS, the 5th day of October, 2015.

Jacqueline H. Ray
Special Assistant Attorney General
Office of the Mississippi Attorney General

SWORN TO AND SUBSCRIBED BEFORE ME, this the 5th day of October, 2016.

NOTARY PUBLIC

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 34478 LINDA G. NESLINE Commission Expires Feb. 13, 2020 RANKIN COUNTY

My Commission Expires:

Exhibit C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
College Park, MD 20740

APR 1 - 2014

Samuel S. Epstein, M.D.
Cancer Prevention Coalition
University of Illinois at Chicago
School of Public Health, MC 922
2121 West Taylor Street, Rm. 322
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RE: Docket Numbers 94P-0420 and FDA-2008-P-0309-0001/CP

Dear Dr. Epstein:

This letter is in response to your two Citizen Petitions dated November 17, 1994 and May 13, 2008, requesting that the Food and Drug Administration (FDA or the Agency) require a cancer warning on cosmetic talc products. Your 1994 Petition requests that all cosmetic talc bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." Additionally, your 2008 Petition requests that cosmetic talcum powder products bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." Further, both of your Petitions specifically request, pursuant to 21 CFR 10.30(h)(2), a hearing for you to present scientific evidence in support of this petition.

We have carefully considered both of your Petitions. We are committed to the protection of the public health and share your interest in reducing the risk of ovarian cancer. Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product. FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate scientific basis on reasonable grounds.

After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.

For this reason and for the additional reasons described below, FDA is denying your Petitions.

APPENDIX.

DEFENSE EXHIBIT
D-473

I. Discussion

The basis of your request, throughout both Petitions, can be summarized as comprising three major points:

1. Talc may be associated with asbestos.
2. Talc is a carcinogen based on the findings of a 1993 National Toxicology Program study.
3. Epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As the points you raise in your Petitions concern the chemistry and toxicology of talc, the epidemiology associated with talc use, and the etiology of ovarian cancer, commensurate reviews were conducted to assess your request.

Chemistry Findings:

Asbestos is a known carcinogen and your first major point is that talc may be associated with asbestos. As evidence that talc cosmetic products contain asbestos, you first cite a 1968 survey of 22 talcum products that found fiber content averaging 19% in all 22 products. This author further concludes that "the fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits …"

You then cite a follow up study from 1971-1975 that examined 21 samples of consumer talcums and powder and concluded that cosmetic grade talc was not used exclusively in these products. This study found the presence of asbestiform anthophyllite and tremolite, chrysotile, and quartz. From these two citations, one may infer that currently available talc-containing cosmetic products are presently contaminated with asbestos, a known carcinogen. Unfortunately, you did not present any original data on the chemical composition of talc currently being used in cosmetics talc products or data linking these findings to currently used talc.

It has been reported in the scientific literature that most talc products in world trade are impure as a result of the geological processes involved in the formation of talc deposits. Further, talc containing asbestos fibers such as tremolite asbestos or chrysotile are sometimes encountered. However, large deposits of high purity, asbestos-free talc do exist and talc purification techniques have been developed which can be used to improve talc quality. Thus, while it has been reported in the past that cosmetic talc has been contaminated with asbestos, it has been also reported that asbestos-free talc deposits do exist. In addition, techniques do exist for the purification of talc in order to improve its quality. You have not provided evidence that asbestos contaminated talc-containing cosmetic products are currently being marketed, since the data submitted is almost 40 years old.

Because safety questions about the possible presence of asbestos in talc are raised periodically, in 2009 FDA conducted an exploratory survey of currently marketed cosmetic-grade raw material talc and finished cosmetic products containing talc. This survey analyzed cosmetic-grade raw material talc from four suppliers out of a possible group of nine suppliers we had requested talc samples from, along with thirty-four talc-containing cosmetic products currently available in the Washington, D.C. metropolitan area for the presence of asbestos. In order to cover as broad a product range as possible, samples identified for testing included low, medium, and high priced products, along with some from "niche" markets. The cosmetic products identified as containing talc included eye shadow, blush, foundation, face powder, and body powder.

The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. While FDA found this data informative, the results were limited by the fact that only four suppliers submitted samples and by the number of products tested. They do not prove that all talc-containing cosmetic products currently marketed in the United States are free of asbestos contamination. As always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health. You may wish to see more on this survey on our website at http://www.fda.gov/Cosmetics/ProductandIngredientSafety/SelectedCosmeticIngredients/ucm293184.htm.

Toxicology Findings:

Your second major point is that talc is a carcinogen with or without the presence of asbestos-like fibers. The basis to this claim is that in 1993, the National Toxicology Program (NTP) published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity.

This NTP report concluded that cosmetic-grade talc caused tumors in animals, even though no asbestos-like fibers were found. The report made the following observations:

- There was some evidence of carcinogenic activity in non-asbestiform talc from inhalation studies in male rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland.
- There was clear evidence of carcinogenic activity of talc in female rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.
- There was no evidence of carcinogenic activity of talc in male or female mice exposed to 6 or 18 mg/cubic meter.

However, this study lacks convincing scientific support because of serious flaws in its design and conduct, including:

- The investigators used micronized talc instead of consumer-grade talc resulting in the experimental protocol not being reflective of human exposure conditions in terms of particle size.

- Investigators conceded that they had problems with the aerosol generation system; whereby, the target aerosol concentrations were either excessive or not maintained during 26 of the 113-122 weeks of the study.
- The study did not include positive and negative dust controls which would have permitted an "exact assessment" of the talc's carcinogenicity relative to the two control dusts.

In light of these shortcomings, a panel of experts at the 1994 ISRTP/FDA workshop declared that the 1993 NTP study has no relevance to human risk.

In addition, we reviewed relevant toxicity literature (consisting of 15 articles from 1980 to 2008), not cited in your Petitions, to determine if there was additional support at this point in time to for your suggested warning label. Scientific literature on studies of acute exposure effects, subchronic exposure effects, chronic exposure or carcinogenicity effects, developmental or reproductive toxicity, and genotoxicity effects were reviewed. As a result of the review of this relevant literature, FDA did not find enough additional support at this point in time for your suggested warning label.

Epidemiology and Etiology Findings:

Your third major point is that epidemiological studies confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

After consideration of the scientific literature submitted in support of both Citizen Petitions, FDA found:

1 The exposure to talc is not well-characterized; it is not known if the talc referred to in the scientific studies was free of asbestos contamination; various consumer brands or lots of talc were not identified; and contamination of talc by asbestiform minerals or other structurally similar compounds was not ruled out.

2 Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk.

3 Results of case-controls studies do not demonstrate a consistent positive association across studies; some studies have found small positive associations between talc and ovarian cancer but the lower confidence limits are often close to 1.0 and dose-response evidence is lacking.

4 A cogent biological mechanism by which talc might lead to ovarian cancer is lacking; exposure to talc does not account for all cases of ovarian cancer; and

5 there was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure.

6 The conclusion of the International Agency for Research on Cancer that epidemiological studies provide limited evidence for the carcinogenicity of perineal use of talc based body powder and the IARC classification of body-powder talc as group-2B, a possible carcinogen to human beings, is persuasive, but the results of the Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever talc use and epithelial ovarian cancer.

Per the etiology review, approximately 10% of epithelial ovarian cancers are associated with inherited mutations. The remaining 90% of epithelial ovarian cancers are not related to these genetic mutations are non-hereditary. They have been historically classified based on histology as borderline/low malignant potential, serous, endometrioid, mucinous, and clear-cell.

Two theories have historically dominated on the cause of epithelial ovarian cancer and these are the "incessant ovulation hypothesis" and the "gonadotropin hypothesis." In addition to these endogenous factors, the role of exogenous factors via retrograde transport of noxious substances (e.g. carcinogens, particulates such as talc and asbestos, endometriosis and infectious agents) from the vagina and uterus into the Fallopian Tubes and peritoneal cavity have been studied extensively as a possible risk factor for ovarian cancer.

While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers. However, there has been no conclusive evidence to support causality.

The best evidence for an association or causal relationship between genital talc exposure and ovarian cancer comes from epidemiologic data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking.

Request for hearing

In addition to your request for a warning label, you also requested a hearing, under 21 CFR 10.30(h)(2), so that you can present scientific evidence in support of your petitions.

Under this regulation, FDA may deny a citizen petition request for a hearing if the data and information submitted (even if accurate), are insufficient to justify the determination urged. In consideration of your request, we conducted an expanded literature search dating from the filing of the petition in 2008 through January 2014. The results of this search failed to identify any new compelling literature data or new scientific evidence.

Since we find that the data and information are insufficient to justify the determination you request and we did not identify any new compelling literature data or new scientific evidence, FDA is also denying your hearing request.

II. Conclusion

FDA appreciates the goals of the Cancer Prevention Coalition and FDA supports the goal of reducing the rate of ovarian cancer. Although FDA is denying the Cancer Prevention Coalition's petitions for the reasons discussed above, the Agency shares your commitment to the public health.

Sincerely,

Steven M. Musser, Ph.D.
Deputy Director for Scientific Operations
Center for Food Safety
and Applied Nutrition

Drafted: J. Gasper, OCAC, 2/28/14
Comments: L. Katz, OCAC, 3/3/14
Revised: J. Gasper, OCAC, 3/4/14
Cleared: N.Sadrieh, OCAC, 3/4/14
Cleared: LMKatz, OCAC, 3/5/14
Reviewed: FHogue, OCAC: 3/614
Cleared by:Musser:3/13/14
F/T:SRussell, OCAC 3/18/14

Exhibit D

Citizen Petition Seeking Carcinogenic Labeling on All Cosmetic Talc Products

November 17, 1994

David A. Kessler, M.D.
Commissioner
Food and Drug Administration, Room 1- 23
12420 Parklawn Drive
Rockville, MD 20857

The undersigned submits on behalf of the Cancer Prevention Coalition, Inc. (CPC), Samuel S. Epstein, M.D., Chair and National Advisor of the Ovarian Cancer Early Detection and Prevention Foundation (OCEDPF), Nancy Nehls Nelson, member of the Ovarian Cancer Early Detection and Prevention Foundation, Peter Orris, M.D. and Quentin Young, M.D. This citizen petition is based on scientific papers dating back to the 1960s which warn of increased cancer rates resulting from frequent exposure to cosmetic grade talc.

The undersigned submits this petition under 21 U.S.C. 321 (n), 361, 362, and 371 (a); and 21 CFR 740.1, 740.2 of 21 CFR 10.30 of the Federal Food, Drug, and Cosmetic Act to request the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases risk of ovarian cancer.

A. AGENCY ACTION REQUESTED
This petition requests that FDA take the following action:

(1) Immediately require cosmetic talcum powder products to bear labels with a warning such as Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer.

(2) Pursuant to 21 CFR 10.30 (h) (2), a hearing at which time we can present our scientific evidence.

B. STATEMENT OF GROUNDS
Ovarian cancer is the fourth deadliest women's cancer in the U.S., striking approximately 23,000 and killing approximately 14,000 women this year. Ovarian cancer is very difficult to detect at the early stages of the disease, making the survival rate very low. Only three percent of ovarian cancer cases can be attributed to family history. (1) One of the avoidable risk factors for ovarian cancer is the daily use of talcum powder in the genital area. (2)

Research done as early as 1961 has shown that particles, similar to talc and asbestos particles, can translocate from the exterior genital area to the ovaries in women. (3,4,5) These findings provide support to the unexpected high rate of mortality from ovarian cancer in female asbestos workers. (6,7,8) Minute particles, such as talc are able to translocate through the female reproductive tract and cause foreign body reactions in the ovary.

There is a large body of scientific evidence, dating back thirty years, on the toxicity and mineralogy of cosmetic talc products. As early as 1968, Cralley et al. Concluded:

APPENDIX.C

DEFENDANT'S EXHIBIT
D-256

> All of the 22 talcum products analyzed have a ...fiber content...averaging 19%. The fibrous material was predominantly talc but probably contained minor amounts of tremolite, anthophyllite, and chrysotile [asbestos-like fibers] as these are often present in fibrous talc mineral deposits...Unknown significant amounts of such materials in products that may be used without precautions may create an unsuspected problem. (9)

As a follow-up to previous findings, Rohl, et al., examined 21 samples of consumer talcums and powders, including baby powders, body powders, facial powders and pharmaceutical powders between 1971-1975. The study concluded:

> ...cosmetic grade talc was not used exclusively. The presence in these products of asbestiform anthophyllite and tremolite, chrysotile, and quartz indicates the need for a regulatory standard for cosmetic talc...We also recommend that evaluation be made to determine the possible health hazards associated with the use of these products.(11,10)

Talc is a carcinogen, with or without the presence of asbestos-like fibers. In 1993, the National Toxicology Program published a study on the toxicity of non-asbestiform talc and found clear evidence of carcinogenic activity (11).

Recent cancer research in the United States has found conclusively that frequent talcum powder application in the genital area increases a woman's risk of developing ovarian cancer (12,13,14,15).

Cramer, et al, suggested that talc application directly to the genital area around the time of ovulation might lead to talc particles becoming deeply imbedded in the substance of the ovary and perhaps causing foreign body reaction (granulomas) capable of causing growth of epithelial ovarian tissue (16,17).

Harlow, et al, found that frequent talc use directly on the genital area during ovulation increased a woman's risk **threefold** . That study also found:

> "The most frequent method of talc exposure was use as a dusting powder directly to the perineum (genitals) . . . Brand or generic 'baby powder?was used most frequently and was the category associated with a statistically significant risk for ovarian cancer.?

In Harlow's report, arguably the most comprehensive study of talc use and ovarian cancer to date, 235 ovarian cancer cases were identified and compared to 239 controls, women with no sign of ovarian cancer or related health problems. Through personal interviews, Harlow, et al, found that 16.7% of the control group reported frequent talc application to the perineum (18). This percentage is useful in estimating the number of women in the general population exposed to cosmetic talc in the genital area on a regular basis. Harlow, et al, concludes:

> ? . . given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For this reason, we discourage the use of talc in genital hygiene, particularly as a daily habit.?

Clearly, large numbers of women—an estimated 17%—are using cosmetic talc in the genital area and may not be adequately warned of the risk of ovarian cancer from daily use.

C. CLAIM FOR CATEGORICAL EXCLUSION

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.24 (a) (11).

D. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

This petition is submitted by:
Jill A. Cashen
Samuel S. Epstein, M.D.
Cancer Prevention Coalition

Michael E. Deutsch, Legal Director
Center for Constitutional Rights

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APPENDIX I: Results for an informal survey of talc products in Chicago drug stores.

BABY POWDERS
Johnson & Johnson Baby Powder. Contains: TALC, fragrance.

Osco Brand Baby Powder. Contains: TALC, fragrance.

Jean Nate Perfumed Talc. Contains: TALC, kaolin, magnesium carbonate, fragrance.

Shower to Shower. Contains: TALC, cornstarch, sodium bicarbonate, fragrance, polysaccarides.

Ammens Medicated Powder. Contains: Zinc oxide, cornstarch, fragrance, isostearic acid, PPG-20, methyl glucose ether, TALC.

Cashmere Bouquet Perfumed Powder. Contains: TALC, magnesium carbonate, zinc stearate, fragrance.

Gold Bond Medicated Powder. Contains: Menthol, zinc oxide, boric acid, eucalyptol, methyl salicylate, salicylic acid, TALC, thymol, zinc stearate.

FEMININE PRODUCTS

Vagisil Feminine Powder. Contains: Cornstarch, aloe, mineral oil, magnesium stearate, silica, benzethonium chloride, fragrance.

Vaginex Feminine Powder. Contains: Zinc oxide, cornstarch, fragrance, 6-hydroxquinoline, 8-hydroxquinoline sulfate, isostearic acid, PPG-20, methyl glucose ether, TALC.

Summer's Eve Feminine Powder. Contains: Cornstarch, tricalcium phosphate, oxoxynol-9, benzethonium chloride, fragrance.

FDS Feminine Deodorant Spray. Contains: Isobutane, isopropyl myristate, cornstarch, mineral oil, fragrance, lanolin alcohol, hydrated silica, magnesium stearate, benzyl alcohol.

Exhibit E

Cancer
Prevention
Coalition

UIC SCHOOL OF PUBLIC HEALTH, MC 922 · 2121 W. TAYLOR ST. · CHICAGO, IL 60612 · (312) 996-2297 · epstein@uic.edu

Cancer prevention through reduction of carcinogens in air, water, food, consumer products, and the workplace
www.preventcancer.com

PETITION SEEKING A CANCER WARNING ON COSMETIC TALC PRODUCTS

May 13, 2008

Mike Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services

Andrew C. von Eschenbach, M.D.
Commissioner of Food and Drugs

Dockets Management Branch
Food and Drug Administration, Room 1601
5630 Fishers Lane
Rockville, MD 20852

Citizen Petition

The undersigned submits this May 13, 2008, Citizen Petition on behalf of: Samuel S. Epstein, M.D., Chairman, Cancer Prevention Coalition (CPC), and Professor emeritus Occupational and Environmental Medicine, University of Illinois at Chicago School of Public Health; Peter Orris, M.D., Professor and Chief of Service, University of Illinois at Chicago Medical Center; Quentin Young, M.D., Chairman, Health and Medicine Policy Research Group, Chicago; Rosalie Bertell, Ph.D., International Association for Humanitarian Medicine, Scientific Advisor to the International Institute of Concern for Public Health, Toronto, and the International Science Oversight Board of the Organic Consumers Association, Washington, D.C.; and Ronnie Cummins, National Director of the Organic Consumers Association.

This Petition, submitted under 21 U.S.C. 321 (n), 361, 362, and 371 (a); and 21 CFR 740.1, 740.2 of 21 CFR 10.30 of the Federal Food, Drug and Cosmetic Act, requests the Commissioner of Food and Drugs to require that all cosmetic talc products bear labels with a warning such as, "Frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer."

A. AGENCY ACTION REQUESTED

This Petition requests FDA to take the following action:

(1) Immediately require cosmetic talcum powder products to bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer."

(2) Pursuant to 21 CFR 10.30 (h) (2), a hearing which will be held at which time we can present scientific evidence in support of this Petition.

B. STATEMENT OF GROUNDS

On November 17, 1994, the Cancer Prevention Coalition and the New York Center for Constitutional Rights submitted a Citizen Petition to the Commissioner of the FDA, "Seeking Carcinogenic Labeling on all Cosmetic Talc Products." The Petition was endorsed by Quentin Young, M.D., Chairman of The Health and Medicine Policy Research Group, Peter Orris, M.D., Director of Health Hazard Evaluation, Cook County Hospital, and Professor of Medicine, University of Illinois Medical School, Chicago, Nancy Nelson, Chair of the Ovarian Cancer Early Detection and Prevention Foundation, and subsequently by Senator Edward Kennedy. In a 1997 statement to the Senate, he requested the FDA to place a cancer warning on the label of talc products, besides other products containing known carcinogens. However, over a decade later his warning remains ignored.

The 1994 Petition was supported by 15 scientific publications. These included nine, from 1983 to 1992, on the major risks of ovarian cancer from the frequent application of brand or generic talc "baby powder" to the genital area of women without any warning of the risks involved. Two of these publications also reported that the genital application of talc could result in its translocation to the ovary.

The scientific basis of the 1994 Petition was further supported by J. Mande, Acting Associate Commissioner for Legislative Affairs of the Department of Health and Human Services. On August 25, 1993, he admitted that "We are aware that there have been reports in the medical literature between frequent direct female perineal talc dusting over a protracted period of years, and an incremental increase in the statistical odds of subsequent development of certain ovarian cancers . . . (However) at the present time, the FDA is not considering to ban, restrict or require a warning statement on the label of talc containing products."

The scientific basis of the 1994 Petition was also admitted by the industry. In an August 12, 1982, article in the *New York Times*, Johnson & Johnson, the manufacturer and retailer of talc dusting powder, stated it was aware of a publication which concluded that frequent genital application of talc was responsible for a three-fold increased risk of ovarian cancer. Warnings of these risks were emphasized by the Cancer Prevention Coalition in November 19, 1994, in letters to Mr. Ralph Larsen, CEO of Johnson & Johnson, and Mr. C.R. Walgreen, Chairman and CEO of Walgreens. Johnson & Johnson was urged to substitute cornstarch, a safe organic

carbohydrate, for talcum powder products, and also to label its products with a warning on cancer risks.

In spite of the scientific evidence, and admission by Johnson & Johnson, the Petition was denied by Dr. John Bailey, FDA's Director of the Office of Cosmetics and Colors, on the basis of the "limited availability" (of Agency resources) and on alleged scientific grounds. Dr. Bailey is currently Director of the industry's Personal Care Products Council.

Evidence for the May 2008 Petition is supported by Edward Kavanaugh, President of the industry's Cosmetic Toiletry and Fragrance Association. In 2002, he admitted that talc is "toxic," that it "can reach the human ovaries," and that prior epidemiological investigations concluded that its genital application increased the risk of ovarian cancer. Further evidence for this Petition is based on 12 publications since 1995, cited below. These confirm the causal relation between genital application of talc and ovarian cancer, and the protective effect of tubal ligation or hysterectomy, preventing the translocation of talc to the ovary.

As Dr. Andrew C. von Eschenbach, former Director of the National Cancer Institute, is aware, the mortality of ovarian cancer for women over the age of 65, has escalated dramatically since 1975, by 13% for white and 47% for black women (1). There are about 15,300 deaths from ovarian cancer each year. This makes it the fourth most common fatal cancer in women after colon, breast and lung.

A case-control study, the largest to date, confirmed the relation between the perineal use of talc and ovarian cancer (2). This has also been confirmed by other reports (3-7). In view of the strength of this evidence, "formal public health warnings" were urged in 1999 (8). An analysis of 16 pooled studies confirmed a statistically significant 33% increased risk of ovarian cancer associated with the perineal use of talc (9). A report by 19 scientists in eight nations worldwide, under the auspices of the International Agency for Research on Cancer, concluded that eight publications confirmed a 30-60% increased risk of ovarian cancer following the perineal application of talc (10). This risk has been confirmed in other reports (11, 12).

The protective effects of tubal ligation or hysterectomy, preventing the translocation of talc from the perineum to the ovary, have also been confirmed (2, 3, 4, 7).

C. CLAIM FOR CATEGORICAL EXCLUSION

A claim for categorical exclusion is asserted pursuant to 21 CFR 25.24 (a) (11).

D. CERTIFICATION

The undersigned certifies, that, to his best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

This petition is submitted by:

Samuel S. Epstein, M.D.
Chairman, Cancer Prevention Coalition
Professor emeritus Occupational and Environmental Medicine
University of Illinois School of Public Health, Chicago

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Exhibit D

Memorandum in Support of Johnson Defendants' Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, ex rel. JIM HOOD, ATTORNEY GENERAL

Civil Action No. 25CH1:14-cv-001207

PLAINTIFF,

v.

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC., VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

DEFENDANTS.

MEMORANDUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

The State asserts a single cause of action: a statutory violation of the Mississippi Consumer Protection Act ("MCPA"), Miss. Code Ann. §§ 75-24-1, *et seq.* The MCPA is Mississippi's version of the Federal Trade Commission Act, and is sometimes referred to as one of many state "Little FTC Acts" across the country. The State claims that Defendants Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Companies, Inc. ("JJCC") engaged in unfair or deceptive trade practices by failing to warn users of certain "Talc Products" (Johnson's® Baby Powder, Shower to Shower®) of the alleged risk of developing ovarian cancer from

frequent use of talcum powder on the genitals.[1] According to the State, the Talc Products' labels are "deceptive and false" under Mississippi law—which, the State claims, mandates that the labels be replaced with new ones bearing a warning that the State asks the Court to craft.

The State has recently clarified that its claim is limited to the *labeling* of the Talc Products. As originally pled, the allegations of the Complaint sounded in false advertising, and appeared to allege that advertisements and other external marketing for the Talc Products were false and misleading. But the State has since voluntarily dismissed any such claims with prejudice, and has and has limited its sole MCPA claim to allegations based on "a product label and/or packaging." Order, Doc. #165 at p. 2.

The State's limitation of its claim renders it ripe for immediate dismissal on summary judgment on purely legal grounds, without the need for any discovery. The labeling of cosmetics is highly regulated by federal law and the Food and Drug Administration. The State's MCPA claim based on product labels theory fails as a matter of law for two independent but equally fatal reasons:

- ***First,*** the State's claim fails because the MCPA simply does not apply to the labeling of cosmetic products. The MCPA expressly relies on its predecessor statute, the federal FTC Act, to define what constitutes an unfair or deceptive trade practice—and the FTC Act expressly *carves out* cosmetic labeling from that definition. In fact, the FTC and the FDA have long agreed that cosmetic product labeling is the province of the FDA, not the FTC. See Memorandum of Understanding, attached as MOTION EXHIBIT "A."

[1] *See* Compl. ¶ 3; Plaintiff's Response to JJCC's First Set of Interrogatories, No. 6, attached as MOTION EXHIBIT "B."

- ***Second,*** even if the MCPA did apply to cosmetics labeling (and it does not), the statute cannot be used as the State attempts here because the FDA has already ruled that there is no scientific basis for adding an ovarian cancer warning to cosmetic talc products. The FDA's decision preempts the State's MCPA claim.

The State asks this Court to (1) issue extraordinary injunctive relief that would extend the scope of a Mississippi statute beyond its scope; (2) ignore the interpretations and self-imposed limits of the federal agency and law on which the MCPA is based, and which the MCPA expressly follows; and (3) substitute the FDA's carefully considered judgment for the State's own unsupported legal theory that contradicts the FDA's scientific conclusion. The Court should grant summary judgment as a matter of law in favor of J&J and JJCC and dismiss the State's claim in its entirety.

BACKGROUND

This is not a personal injury case. The State's complaint does not allege that a single Mississippi resident has been injured by using the Talc Products. Nor does the complaint identify even one injured Mississippian.

Instead, the State alleges that both J&J and JJCC have violated the MCPA by engaging in "unlawful, unfair, and deceptive business practices related to the manufacturing, sale, and marketing of their talc-containing products . . . [by] failing to warn . . . that women using these products on their genital area (also known as perineal use) are at an increased risk of ovarian cancer."[2] *See* Pl.'s Compl. at p. 2, ¶ 3. The State's claim for injunctive relief seeks the court-compelled imposition of an unspecified warning that perineal use of talc can cause ovarian

[2] J&J does not manufacture, market, or distribute *any* product of any kind. It has never advertised or distributed the Talc Products at issue in this case, and it has never conducted business in the State of Mississippi. *See, e.g.,* J&J Answer, Doc. # 55 at Third Defense, p. 2; Johnson Defendants' Motion to Dismiss, Doc. # 16 at ¶ 2 & Ex. A, Affidavit of Lacey P. Elberg, ¶ 8.

cancer. *See id*. at p. 3, ¶ 6, pp. 30–31, ¶ 96, at pp. 31–32 (prayer for relief). The FDA has directly considered and rejected the very same proposed warning on talc products. *See* MOTION EXHIBIT "C," FDA Denial Letter at 4–5 (April 1, 2014) (rejecting proposed warnings about ovarian cancer risk from perineal use of talc). The State asks this Court to supplant the FDA's judgment with its own, and to mandate a warning—presumably to be crafted by this Court—under color of the MCPA.

This motion is limited to issues of law arising from the State's clarification that its claim is limited to the labeling of the Talc Products. J&J and JJCC maintain that (1) the MCPA does not apply to the labeling of FDA-regulated products, including these Talc Products; and (2) even if the MCPA did apply, the State's claim would be preempted by federal law. (*See* Answers and Defenses of J&J at 5 and JJCC at 5).[3]

LEGAL STANDARD

Summary judgment should be granted where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Miss. R. Civ. P. 56(c); *see also Leitch v. Miss. Ins. Guar. Ass'n*, 27 So. 3d 396, 398 (Miss. 2010). The moving party must demonstrate that no genuine issue of material fact exists which would preclude the entry of judgment as a matter of law. *Waggoner v. Williamson*, 8 So. 3d 147, 152–53 (Miss. 2009).

[3] J&J and JJCC further maintain there is no liability at all under the MCPA given the present state of the science regarding talc use and ovarian cancer, *see, e.g.*, *Carl v. Johnson & Johnson*, No. ATL-L-6546-14, 2016 WL 4580145 (N.J. Super L. Sept. 2, 2016) (finding insufficient evidence to create a jury question on the issue of whether the Talc Products cause ovarian cancer and entering summary judgment in favor of J&J and JJCC); *cf. In re Johnson & Johnson Talcum Powder Cases*, No. BC628228, 2017 WL 4780572 (Cal. Super. Oct. 20, 2017), and that the State's claim for injunctive relief is also barred by the First Amendment's prohibition against compelled speech. These issues are preserved and, if necessary, will be presented to the Chancery Court by motion after the completion of discovery.

ARGUMENT

J&J and JJCC are entitled to summary judgment as to the State's labeling claim for two independent reasons. First, judgment is appropriate because the MCPA does not apply to the labeling of cosmetic products. Second, even if the MCPA did apply, the State's labeling claim is preempted by federal law under the circumstances of this case.

I. THE MCPA DOES NOT APPLY TO COSMETIC PRODUCT LABELING

A. The MCPA, by Its Express Terms, Follows the Federal FTC Act

The MCPA, originally enacted in 1974, prohibits "[u]nfair methods of competition affecting commerce and unfair or deceptive trade practices in or affecting commerce." Miss. Code Ann. § 75-24-5(1). The Act was derived from the Federal Trade Commission Act ("FTCA" or "FTC Act"). Indeed, the MCPA and similar statutes enacted by other states are sometimes referred to as "Little FTC Acts." *See, e.g.*, *Deadwyler v. Volkswagen of Am., Inc.*, 748 F. Supp. 1146, 1151–52 (W.D.N.C. 1990). *See generally* John C.P. Goldberg et al., *The Place of Reliance in Fraud*, 48 Ariz. L. Rev. 1001, 1015–16 (2006) (discussing the states' adoption of statutes modeled after the FTCA).

The MCPA does not define what constitutes an unfair or deceptive trade practice under the Act. Instead, the MCPA expressly provides that "in construing what constitutes unfair or deceptive trade practices," courts must look to the FTCA and how it has been interpreted. *See* Miss. Code. Ann. § 75-24-3(c). The Mississippi Supreme Court has confirmed this principle in both *In re Mississippi Medicaid Pharmaceutical Average Wholesale Price Litigation*, 190 So. 3d 829, 841–42 (Miss. 2016) ("*Sandoz*") and, most recently, in *Watson Labs, Inc. v. State*, No. 2014-CA-01213-SCT, slip op. at 28–29, ¶¶ 46–47, 2018 WL 372297, at *12 (Miss. Jan. 11, 2018) (affirming chancellor's use of "guidance from the Federal Trade Commission and federal-

court precedent of analogous federal statutes"). Thus, when deciding what conduct is actionable under the MCPA, Mississippi courts must construe the state statute in accordance with its federal parent law, and must look to what acts can trigger liability under the FTCA.

B. Allegedly False Labeling Does Not Constitute an Unfair or Deceptive Trade Practice under the FTC Act or the MCPA

These principles doom the State's claim, because the FTCA expressly exempts product labeling from the statute's reach. Specifically, the FTCA defines an "unfair or deceptive act or practice" to include "the dissemination or the causing to be disseminated of any false advertisement." 15 U.S.C. § 52. The FTCA then goes on to define a false advertisement as "an advertisement, *other than labeling*, which is misleading in a material respect." 15 U.S.C. § 55(a)(1) (emphasis added).

Courts have recognized this limitation of the FTCA's reach. *See, e.g., Miles Labs., Inc. v. FTC*, 50 F. Supp. 434, 437 (D.D.C. 1943) ("The dissemination of a 'false advertisement' by a corporation *otherwise than on the labels* carried by its products is an unfair or deceptive act or practice which is declared unlawful and which the Federal Trade Commission is empowered and directed to prevent.") (emphasis added), *aff'd*, 140 F.2d 683 (D.C. Cir. 1944); *FTC v. Willms*, No. 11-CV-828, 2011 WL 4103542 (W.D. Wash. Sept. 12, 2011). Because the MCPA expressly relies upon the FTCA in "construing what constitutes an unfair or deceptive act" within the scope of the statute, the MCPA is likewise constrained. Miss. Code Ann. § 75-24-3(c).

The exemption of cosmetic labeling from the scope of the FTCA (and consequently from the scope of the MCPA) is further demonstrated by a Memorandum of Understanding entered into by the FTC and FDA, which was in effect when the Mississippi Legislature enacted the MCPA in 1974. The Memorandum provides that the FTC regulates the "advertising" of products, including foods, drugs, devices and cosmetics, and the FDA regulates their "labeling."

(*See* MOTION EXHIBIT "A," FDA/FTC Memorandum, 36 Fed. Reg. 18,539 (1971) (the FTC "has primary responsibility with respect to the regulation of the truth or falsity of all advertising (*other than labeling*) of foods, drugs, devices, and cosmetics" and the FDA "will exercise primary jurisdiction over all matters *regulating the labeling* of foods, drugs, devices, and cosmetics") (emphasis added)). This Memorandum, which has not been amended, remains in force today, and further demonstrates that cosmetics labeling is a matter for the FDA—not for the FTC, the FTCA, or "Little FTCAs" like the MCPA.

Importantly, recourse for improper labeling of cosmetics is available through federal agency action—but *not* the federal authority undergirding the State's statutory claim in this case. Rather, it is the Food, Drug, and Cosmetics Act ("FDCA")—not the FTCA—which assigns to the FDA (not the FTC or the Mississippi Attorney General) the tasks of "reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and ensuring that "cosmetics are safe and properly labeled." *See* 21 U.S.C. § 393(b)(1), (b)(2)(D). The FDA may regulate the "requirements" for the labeling of cosmetics through its own initiative and through the citizen petition process. *See* 21 C.F.R. §740.1(b). FDA regulations require that "[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing." 21 C.F.R. § 740.10(a). The FDCA prohibits manufacturers from selling "adulterated" or "misbranded" cosmetics, and imposes penalties for doing so. *See* 21 U.S.C. §§ 331(a), 361-62(a)–(d).

Simply put, the MCPA looks to the FTCA and cases interpreting it for guidance as to what constitutes unfair or deceptive trade practices, and the FTCA and those authorities are abundantly clear that product labeling is outside the scope of covered conduct. This Court should hold that the MCPA does not authorize the State's claim concerning FDA-regulated

cosmetic labeling—especially since the State seeks to undermine, and not to follow, the federal authority which actually applies here.

II. FEDERAL LAW PREEMPTS THE STATE'S MCPA CLAIMS

The State's Complaint must be dismissed for the independent and additional reason that its MCPA claim is preempted by federal law. The preemption analysis is straightforward and well-established. The FDCA expressly preempts any state-law imposition of a "requirement for labeling or packaging of a cosmetic" that is not "identical with" the FDA's own labeling requirements. 21 U.S.C. § 379s. Here, there is absolutely no doubt that the State's proposed label warning is "not identical" with what the FDA requires: the same year that the Complaint was filed, the FDA rejected a petition to require precisely such a warning, giving detailed reasons why any supposed association between talc and ovarian cancer was not scientifically supported. That ends the inquiry: in attempting to impose a warning that the FDA has rejected, the State's action is expressly preempted by federal law.

Moreover, even if there were no express preemption under federal law—and there is—the State's claim would still be preempted under implied preemption principles. The State's claim would open the door for differing labeling regulations imposed by all 50 states and would undercut the clear congressional intent for the FDA to have full, consistent regulatory authority over cosmetic labeling. The State's claim must be dismissed.

A. The FDA Regulates Cosmetics Labeling and Determines when Warnings Are Appropriate

The FDA regulates cosmetic products pursuant to the FDCA, 21 U.S.C. § 301 *et seq*. The FDA's oversight extends to talc-based cosmetics, such as the Talc Products at issue in this case. *See* FDA, *Talc*, http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184 (last visited Jan. 26, 2018) (explaining that "FDA monitors for potential safety problems with cosmetic products on the market," including those with talc, "and takes action when needed to protect public health").

With respect to labeling, the FDCA prohibits cosmetics labeling that is "false or misleading in any particular." 21 U.S.C. § 362(a). The FDCA's implementing regulations further provide that the labeling of a cosmetic product "shall be deemed to be misleading if it fails to reveal facts that are . . . [m]aterial with respect to consequences which may result from use" of the product. 21 C.F.R. § 1.21. In particular, a cosmetic label "shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." 21 C.F.R. § 740.1(a). Critically, the regulations provide that the FDA is tasked with determining when such a warning is "necessary or appropriate": "The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish . . . a regulation prescribing a warning for a cosmetic. . . ." 21 C.F.R. § 740.1(b).

B. The FDCA Expressly Preempts All State Law Claims that Seek to Impose Labeling that Is "Not Identical" to FDA Requirements

The FDCA contains an express preemption provision that provides that states may not "establish or continue in effect any requirement for labeling or packaging of a cosmetic that is *different from or in addition to, or that is otherwise not identical with*, a requirement specifically

applicable to a particular cosmetic or class of cosmetics under this Act . . . ." 21 U.S.C. § 379s(a) (emphasis added). "Under this standard, preemption is certainly appropriate when a state law prohibits labeling that is permitted under federal law. But it is *also* appropriate when a state law prohibits labeling that is *not prohibited* under federal law." *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375 (S.D.N.Y. 2014) (emphasis in original). "The standard, in other words, is not whether a state law actively undermines federal law. It is whether state law diverges from federal law *at all*." *Id.* (emphasis in original). Or, as another court explained, state law causes of action are preempted "where they impose obligations not imposed by federal law." *In re PepsiCo, Inc.*, 588 F. Supp. 2d 527, 532 (S.D.N.Y. 2008). Consequently, the State is prohibited from pressing a claim under state law, including the MCPA, that the Talc Products must contain any warning not required by the FDA, or otherwise cannot be sold in Mississippi absent some other, non-FDA-required change to the product labeling or packaging.

For the State to establish that its MCPA claim is not preempted, it would need to show that its labeling claim is "identical with" what the FDA has required. *See Bowling*, 65 F. Supp. 3d at 376. Put another way, the State must demonstrate that the Talc Products' labels actually violate the FDCA and its implementing regulations, because in the face of the FDCA's express preemption clause, "only violations of federal requirements [may] give rise to liability under state law." *O'Connor v. Henkel Corp.*, No. 14 Civ. 5547, 2015 WL 5922183, at *5 (E.D.N.Y. Sep. 21, 2015).

C. The FDA Has Rejected the State's Claim that Talc Product Labeling Needs to Include Ovarian Cancer Warnings

Unlike other cosmetic products, the FDA has not required *any* warnings regarding talc. In fact, the same year this suit was filed, the FDA considered and *expressly rejected* the central

claim raised by the State in this case: that cosmetic talc products should be labeled for a risk of ovarian cancer.

In 1994, the Cancer Prevention Coalition ("CPC") initially submitted a Citizen's Petition to the FDA under the FDCA and the FDA's duly promulgated regulations governing the labeling of cosmetics,[4] requesting that the FDA mandate all cosmetic talc products to bear labels with a warning that "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." *See* MOTION EXHIBIT "D." On May 13, 2008, the CPC submitted a second Citizen's Petition, which requested that the FDA mandate that all cosmetic talcum powder products bear labels with a warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer." *See* MOTION EXHIBIT "E." This Petition insisted that evidence since 1995 had "confirm[ed] the causal relation between genital application of talc and ovarian cancer." *Id.* at 3.

In 2014, the FDA rejected the warnings requested in the Citizen's Petitions—and thereby shattered the fundamental premise of the State's claim in this case. In a comprehensive response, the FDA systematically rejected each argument contained in the Petitions. The FDA even explained that one of the major studies cited in the Petitions—*which the State relies on in its complaint*—"lacks convincing scientific support because of serious flaws in its design and conduct." MOTION EXHIBIT "C" at 3–4; *see id.* at 4 (noting that the study has been condemned as having "no relevance to human risk"); *see also* Compl. ¶ 64 (citing approvingly to the study without mentioning that it has been discredited).

[4] *See* 21 C.F.R. § 740.1(a) ("The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."), *id.* § 740.1(b) (requirements for changes in the labeling of a cosmetic may be initiated by the FDA or through the citizens petition process when the petition is supported by an "adequate factual basis" and it "contains reasonable grounds" for the proposed regulation). For those FDA regulations that generally govern the citizens petition process and authorize judicial review of the FDA's final administrative action taken on a citizen's petition, see 21 C.F.R. §§ 10.20, 10.25, 10.30, 10.45.

In denying the relief sought in the Petitions, the FDA found fundamental deficiencies in the "evidence" upon which the CPC based its position, including:

- "Several of the studies acknowledge biases in the study design and no single study has considered all the factors that potentially contribute to ovarian cancer, including selection bias and/or uncontrolled confounding that result in spurious positive associations between talc use and ovarian cancer risk."
- "Results of case-control studies do not demonstrate a consistent positive association across studies."
- "A cogent biological mechanism by which talc might lead to ovarian cancer is lacking."
- "[T]here was no scientific consensus on the proportion of ovarian cancer cases that may be caused by talc exposure."
- IARC concluded there was "limited evidence for the carcinogenicity of perineal use of talc based body powder."
- The "Nurses' Health Study, a large prospective cohort study, revealed no overall association with ever [sic] talc use and epithelial ovarian cancer."

MOTION EXHIBIT "C" at 4–5. The FDA noted that under its regulations, "FDA may publish a proposal to establish a regulation prescribing a warning statement on behalf of a petitioner if the petition is supported by adequate basis on reasonable grounds." Nonetheless, the FDA concluded:

> After careful review and consideration of the information submitted in your Petitions, the comments received in response to the Petitions, and review of additional scientific information, this letter is to advise you that FDA is denying your Petitions. *FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer.*

Id. at 1 (emphasis added); *see id.* at 5 ("there has been no conclusive evidence to support causality" and "the evidence is insufficient for FDA to require as definitive a warning as you are seeking"); *see* 21 C.F.R. § 740.1(a), (b). The FDA's denial is "final agency action." *See*

Schering Corp. v. Food & Drug Admin., 51 F.3d 390, 393 (3d Cir. 1995) (citing 21 C.F.R. § 10.45). The CPC did not challenge the FDA's ruling.

D. The FDA's Determination Preempts the State's Claim

As set forth above, the FDA has rejected the central premise of the State's claim. That is, the FDA—the agency that federal law tasks with determining the necessity of cosmetic warning labels, *see* 21 C.F.R. § 740.1(b)—determined that a warning about ovarian cancer is *not* required on the labeling of cosmetic talc products. Pursuant to the FDCA's express preemption provision, this determination bars the State's present attempt to require the already rejected warning. *See* 21 U.S.C. § 379s(a) (preempting any labeling requirement that is "different from or in addition to, or that is otherwise not identical with" the FDA's own requirements); *In re PepsiCo Inc.*, 588 F. Supp. 2d 527, 538 (S.D.N.Y. 2008) ("Where federal requirements address the subject matter that is being challenged through state law claims, such state law claims are preempted to the extent they do not impose identical requirements."). In short, the State is asking this Court to fashion warnings regarding ovarian cancer that the FDA has explicitly refused to require on talc products and has rejected as not scientifically substantiated.

There can be no doubt that the State's claim in this lawsuit, as well as its requested remedies, constitutes an attempt to use state law to "establish or continue in effect a[] requirement for labeling or packaging of a cosmetic" that the FDA has directly rejected. 21 U.S.C. § 379s(a); *see also id.* § 379s(c) (clarifying that the scope of preemption encompasses any "any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics" under the FDCA). As the United States Supreme Court explained when interpreting the term "requirement" in another federal preemption statute, the word "sweeps broadly and suggests no distinction between

positive enactments and common law[, and] . . . easily encompass[es] obligations that take the form of common law rules" as well as "some form of preventive relief." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992); *see also Moe v. MTD Products, Inc.*, 73 F.3d 179, 182–83 (8th Cir. 1995) (federal statute expressly preempted state law failure to warn claim whose effect was to "require different or additional warnings about the same risk of injury"). It is well settled that the term "requirements" encompasses attempts by the State to enforce "negative *prohibitions*," as it seeks to do here. *Cippollone*, 505 U.S. at 522 (emphasis in original); *see Cooper v. General Motors Corp.*, 702 So. 2d 428, 436 (Miss. 1997) (following *Cippollone*'s rationale); *Wansley v. Wansley*, No. 251-98-1259CIV, 2002 WL 32091072, at *10 (Hinds Cty. Cir. Ct., Miss., Aug. 28, 2002) (collecting cases and holding, where plaintiffs alleged personal injury claims based on a failure to warn and defective design, that "[a]llowing Plaintiffs to recover on their state law claims against [Defendant] would have the practical effect of imposing a state law requirement" in violation of federal preemption statute). The State's MCPA claim is expressly preempted by 21 U.S.C. § 379s.[5]

Courts have consistently found state law claims preempted under similar circumstances. For example, in *Bimont v. Unilever U.S., Inc.*, the plaintiffs filed suit against a deodorant manufacturer, alleging that the labeling of the cosmetic violated state consumer protection statutes because it misled consumers about the amount of deodorant in the product. No. 14 Civ. 7749, 2015 WL 5256988, at *1 (S.D.N.Y. Sept. 9, 2015). The court explained that state law claims are preempted under the FDCA "if they (1) impose any non-identical requirement on

[5] To be sure, when enacting Section 379s, Congress included a "savings clause" that expressly preserves "any action or the liability of any person under the product liability law of any State." *See* 21 U.S.C. § 379s(d). But this is not a product liability case, nor is there any basis for expanding the word "product liability" beyond its plain meaning. A savings clause cannot be interpreted "to thwart and undermine the entire purpose and language of" the federal act. *See Cooper*, 702 So. 2d at 440.

conduct that could be regulated by the FDA; (2) impose any non-identical requirement on conduct whose subject matter has been regulated by the FDA; or (3) impose any conflicting requirement on conduct that has been regulated by the FDA." *Id.* at *3 (citations omitted).

The *Bimont* court concluded that the plaintiffs' state law claims were preempted because "the FDA was given a specific invitation to regulate" the complained-of conduct, but declined to do so. *Id.* at *6. This FDA decision, the court reasoned, was "strong evidence" that the FDA thought the plaintiffs' proposed labeling was unwarranted. *Id.* at *6. As the court explained, the central preemption inquiry is what federal law *requires*. *See id.* at *8; *see also Bowling*, 65 F. Supp. 3d at 376 (dismissing state claims as preempted because plaintiffs failed to plead facts "suggesting that the FDA has affirmatively *prohibited* the label" alleged to violate state law).

The same logic applies here and requires preemption of the State's labeling claim. The State's entire case is built upon the premise that J&J and JJCC "have not and do not warn . . . on the product labeling . . . that the use of their Talc Products in the genital area increases the risk of contracting ovarian cancer." *See* Compl. ¶ 30. But the FDA has determined that the warning the State seeks is *not* required—and "[w]here there is no federal requirement, there can be no state or common law liability." *O'Connor v. Henkel Corp.*, No. 14 Civ. 5547, 2015 WL 5922183, at *11 (E.D.N.Y. Sept. 21, 2015).

And in a case in Mississippi Circuit Court, Circuit Judge Yerger analyzed plaintiffs' state law "off throttle" tort claims and found them preempted by the express preemption provision of the Federal Boat Safety Act ("FBSA"). *Wansley*, 2002 WL 32091072 at *10. The preemption statute at issue in *Wansley* also prohibits the establishment through state law of "any requirement . . . that is not identical to" those established by the relevant federal authority. In granting summary judgment and dismissing the claims as preempted, the court noted:

> The Coast Guard has reviewed personal watercraft design and safety issues since at least 1976. The Coast Guard has heard, considered and rejected a number of proposed suggestions regarding personal watercraft. Contrary to the arguments advanced by Plaintiffs, the evidence shows that the Coast Guard has actually evaluated the "off throttle" steering issue and has chosen not to regulate personal watercraft in this regard.

Id. Given that the plaintiffs were seeking to impose a requirement for which the federal authority had "actually evaluated" and "rejected a number of proposed suggestions," the Court in a very straightforward analysis held that the plaintiff's claims were preempted by state law, and granted summary judgment in favor of the defendants.

E. The State's Claim Must Also Be Dismissed Under the Doctrine of Implied Preemption

In addition to being expressly preempted, the State's claim also falls squarely within the scope of the doctrine of implied federal preemption, which provides additional and alternative bases for dismissal of the claim. *Cf. Wansley*, 2002 WL 32091072, at *10-11 (claim under state law invalid under both express and implied preemption principles).

First, under the doctrine of so-called obstacle preemption, "[a] state law also is pre-empted if it interferes with the methods by which the federal statute was designed to reach th[at] goal." *Int'l Paper Co. v. Ouellette,* 479 U.S. 481, 494 (1987). Put another way, when a state action interferes or undermines the effect of the operation of the federal law, a conflict (or obstacle) develops, which must be resolved in favor of federal preemption. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000) (finding preemption where "state law undermine[d] the intended purpose and 'natural effect' of" federal law); *see also Resolution Trust Corp. v. Diamond*, 45 F.3d 665, 674–75 (2d Cir. 1995) (finding preemption of state law that directly interferes with the "accomplishment and execution of the full purposes and objectives of Congress"). In this instance, the application of the doctrine turns on the FDA's capacity to exercise its authority over cosmetic labeling unhindered by conflicting state action.

Here, the State's MCPA claim both disrupts the federal framework governing the labeling of cosmetics and interferes with the FDA's enforcement under that framework. If permitted, every State could give itself independent authority to prosecute labeling claims against these FDA-regulated cosmetics, thereby diminishing the federal government's control over enforcement and detracting from the integrated scheme of regulation created by Congress. Such a result—diffuse, inconsistent, and even conflicting labeling authority over cosmetics—would clearly depart from congressional intent and impermissibly interfere with the operation of a federally regulated framework. Therefore, the State's claim is preempted.

The Circuit Court's decision in *Wansley* is instructive on this point, as well. As noted above, the *Wansley* court found Mississippi claims preempted both by the express federal statute and under the doctrine of implied preemption. With regard to implied preemption, the Court found that plaintiffs' claims would "'prevent or hinder the FBSA from operating the way Congress intended it to operate.'" *Id.* at *11 (quoting *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir.1997)). The court noted that in addition to opening the door for different and potentially conflicting requirements in each of the 50 states, the plaintiffs' theory would also have conflicted with the federal authority's decision not to impose the requested requirement. *See id.* As the court noted, "a 'federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left unregulated, and in that event would have as much preemptive force as a decision to regulate.'" *Id.* (quoting *Lewis*, 107 F.3d at 1502). Because the federal government had in fact received proposals concerning, and actually considered, the off-throttle steering issue and chosen not to regulate it, implied preemption barred plaintiffs' claims. The same is true here.

Second, states cannot impose damages on companies for doing what federal law "authorized them to do." *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 318 (1981) (after the Interstate Commerce Commission approved a railroad's decision to abandon a branch line, state law could not be used to seek damages for the same); *see also, e.g.*, *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 155 (1982) (federal regulation that permitted, but did not require, federal savings and loan associations to use certain provisions in loan instruments preempted California law that prohibited the same); *Alessi v. Raybestos-Manhattan, Inc.*, 451 U.S. 504, 524 (1981) (ERISA preempts state law which "eliminates one method for calculating pension benefits . . . that is permitted by federal law"); *Cooper*, 702 So. 2d at 435 (federal preemption prevents imposition of state law liability upon a product manufacturer "for exercising a federally sanctioned choice. It would create an actual and definitive conflict."). Where the state law deprives the defendant of an option that federal law permits, the putative state-law requirement is preempted. Under that principle, the State's claim here is preempted. The FDCA, as enforced by the FDA, authorizes manufacturers of talc products to market those products without ovarian cancer warnings on their product labels. The State cannot use the MCPA to reject that authorization.

Third, as has been held with respect to the FDA's regulation of drugs, when "the FDA has made a conclusive determination, positive or negative, as to the existence of a link between the drug at issue and some adverse health consequence, state law cannot mandate that a manufacturer include additional warnings beyond those that the FDA has determined to be appropriate to the risk." *Perry v. Novartis Pharma. Corp.*, 456 F. Supp. 2d 678, 685–86 (E.D. Pa. 2006). Such reasoning applies here, too, where the FDA has weighed the evidence on cosmetic talc safety and declined to mandate the requested warnings. Therefore, the State's

MCPA labeling claim is barred. *See also Carter v. Novartis Consumer Health Inc.*, 582 F. Supp. 2d 1271, 1286 n.25 (C.D. Cal. 2008) (rejecting an injunction forcing the manufacturers of over-the-counter cough and cold medicines to take their products off the shelves as to children younger than six as requiring a change in product labeling that would intrude upon the FDA's regulatory authority).[6]

In sum, the State is trying to do exactly what Congress "sought to forbid: using state law causes of action to bootstrap labeling requirements that are 'not identical with' federal regulation." *Bowling*, 65 F. Supp. 3d at 376. The FDA has been clear that cosmetic talc products are not required to bear an unnecessary warning about an unsubstantiated risk of ovarian cancer. The FDA's decision is dispositive, and federal law preempts, both expressly and impliedly, state claims that impose "additional" or "not identical" requirements on cosmetics makers. Accordingly, the State's MCPA claim is preempted and must be dismissed.

CONCLUSION

Defendants J&J and JJCC are entitled to summary judgment and dismissal of the Complaint on two independent grounds. First, by operation of state statute, the Mississippi Consumer Protection Act does not encompass the State's challenge to the labeling of an FDA-regulated cosmetic product. The State provides no other basis for relief.

Second, J&J and JJCC are separately entitled to summary judgment by operation of federal preemption. The Food, Drug, and Cosmetic Act expressly preempts state actions that

[6] Furthermore, in the drug context, courts have found frequently preemption based on rejections by the FDA of Citizen's Petitions seeking warnings. *See, e.g.*, *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 930 (6th Cir. 2014); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) ("The 'clear evidence' in this case is the agency's refusal to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, when it had been asked to do so in the submission [*i.e.*, citizen petition] to which the agency was responding."); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 15 Civ. 3941, 2017 WL 5455429, at *7 (N.D. Ill. Nov. 14, 2017).

diverge from specifically applicable federal requirements, and impliedly preempts, at minimum, state actions that seek to impose labeling requirements that have been rejected by the FDA. The State's requested labeling change was previously—and properly—brought to the FDA, and the FDA determined that the warning requested was not necessary or warranted. That determination preempts the State's attempt to resurrect the claim here.

DATED: January 26, 2018

Respectfully submitted,

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THIS the 26th day of January, 2018.

/s/ *Meade W. Mitchell*
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Exhibit E

Valeant Defendants' Joinder in Johnson Defendants' Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, ex rel. JIM HOOD, ATTORNEY GENERAL	**PLAINTIFF**
v.	**CIVIL ACTION NO. 25CH1:14-cv-001207**
JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	**DEFENDANTS**

VALEANT PHARMACEUTICALS INTERNATIONAL, INC. AND VALEANT PHARMACEUTICALS NORTH AMERICA, LLC'S JOINDER TO DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.'S MOTION FOR SUMMARY JUDGMENT

Come Now Defendants Valeant Pharmaceuticals International, Inc.[1] and Valeant Pharmaceuticals North America, LLC (collectively "Valeant"), and join Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc.'s (collectively "Johnson & Johnson") Motion for Summary Judgment [Dkt. 248] (the "Motion") and Memorandum in Support thereof [Dkt. 249]. Valeant hereby joins and incorporates herein all arguments, authorities, exhibits, background and relief sought in the Motion and Memorandum submitted by Johnson & Johnson on January 26, 2018. Summary judgment should issue to Valeant for the same reasons it should issue to Johnson & Johnson.[2]

INTRODUCTION AND PROCEDURAL HISTORY

Plaintiff filed suit against Valeant and Johnson & Johnson in August 2014, claiming they engaged in unfair and deceptive trade practices with respect to the marketing of the Shower to

[1] Valeant Pharmaceuticals International, Inc. is not involved with the manufacture, labeling, marketing, or sale of Shower to Shower®.

[2] Valeant reserves the right to raise additional bases for summary judgment in this action at the close of discovery and in the event this Motion is denied in whole or in part.

Shower body powder, which was marketed by Johnson & Johnson until October 2012 when it sold the distribution rights to Valeant. Plaintiff also asserted similar claims with respect to Johnson & Johnson's Baby Powder product. Plaintiff alleges that Johnson & Johnson, and later Valeant, engaged in "unlawful, unfair, and deceptive business practices related to the manufacturing, sale and marketing of their talc-containing products…[by] failing to warn…that women using these products on their genital area (also known as perineal use) are at an increased risk of ovarian cancer." See Plaintiff's Complaint [Dkt. 002] at p. 2, ¶3. The Complaint seeks injunctive relief in the form of a warning added to the labeling of the talc-containing products described in the Complaint, as well as civil penalties and disgorgement of profits from the sale of the talc-containing products within Mississippi. Compl. [Dkt. 002] at p.3 ¶6, pp. 30-32 ¶96 and prayer for relief.

On January 26, 2018, Johnson & Johnson filed its Motion for Summary Judgment [Dkt. 248] and Memorandum in Support [Dkt. 249], explaining that the Mississippi Consumer Protection Act does not apply to the labeling of cosmetic products and the claims asserted in this case are preempted because only the United States Food and Drug Administration ("FDA") may regulate the labeling and marketing of cosmetic products. The Motion has been set by agreement of the parties for hearing on March 22, 2018; Defendants have agreed Plaintiff's Response to the Motion will be filed on or before February 23, 2018. Because Valeant does not advance additional arguments or request any additional relief, joinder in this Motion will not impact Plaintiff's ability to respond timely and will not require the Court to consider additional issues not raised in the original Motion. The grounds for the Motion and the relief sought are identical as to all defendants.

ARGUMENT

Plaintiff's claims against both Johnson & Johnson and Valeant are identically pled under the Mississippi Consumer Protection Act ("MCPA"), Miss. Code Ann. 75-24-5(1), and thus Plaintiff's claims against Valeant must fail for the same reasons outlined in Johnson & Johnson's Motion and Memorandum of Law. The MCPA expressly incorporates the Federal Trade Commission Act ("FTCA"), 15 U.S.C. §45, *et seq*., which does not apply to the labeling of cosmetics. *See* Miss. Code Ann. §75-24-3(c). Instead, as Johnson & Johnson demonstrates in its Motion and Memorandum of Law, regulation of cosmetic labeling is reserved for the FDA through the Food, Drug and Cosmetics Act ("FDCA"). 21 U.S.C. §393(b)(1), (b)(2)(D). Because the MCPA does not apply to products such as those at issue in this lawsuit, Plaintiff's MCPA claims must fail and summary judgment should issue.

Additionally, because the FDCA contains an express preemption clause that prohibits state law from imposing a "requirement for labeling or packaging of a cosmetic" that is not "identical with" FDA's labeling requirements, 21 U.S.C. §379s, these claims are expressly preempted by federal law. In this instance, FDA has specifically declined to require warning labeling for talc containing products warning of the risks Plaintiff seeks to have added to the label through the injunctive relief requested in this lawsuit. *See* 2014 FDA Denial of Citizen Petition, attached as Exhibit C to Johnson & Johnson's Motion for Summary Judgment [Dkt. 248-3]. Further, because the FDA alone has been charged with responsibility for regulating cosmetic labeling and has rejected a request to require the very same warning labeling sought in this case, Plaintiff's claims are also impliedly preempted. As Johnson & Johnson's Motion and Memorandum of Law amply demonstrate, many courts have held that claims similar to those pled here, alleging a duty to add a warning label to an FDA-regulated cosmetic, are preempted

by federal law.[3] The claims asserted in this lawsuit against Valeant are preempted for the same reasons articulated by Johnson & Johnson, and this Court should enter summary judgment on this basis as to all claims and all defendants.

CONCLUSION

For the same reasons set forth in the Motion for Summary Judgment [Dkt. 248], Valeant hereby respectfully requests the Court to enter judgment and dismissal of all claims against all defendants in this lawsuit. Valeant further requests any such further and additional relief as the Court deems appropriate.

THIS, the 9th day of February, 2018.

Respectfully submitted,

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[3] Valeant previously asserted preemption as a defense in its Answers [Dkt. 53 and Dkt. 162].

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I, Elizabeth R. Hadley, hereby certify that on this day I have electronically filed the foregoing with the Clerk of the Court using the MEC system which sent notification of such filing to the following counsel of record:

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Exhibit F

Johnson Defendants' Reply in Support of Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, ex rel. JIM HOOD, ATTORNEY GENERAL

Civil Action No. 25CH1:14-cv-001207

PLAINTIFF,

v.

JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC., VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; and VALEANT PHARMACEUTICALS NORTH AMERICA, LLC

DEFENDANTS.

REPLY MEMORANDUM IN FURTHER SUPPORT OF MOTION FOR SUMMARY JUDGMENT BY DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER COMPANIES, INC.

In their moving papers, Johnson & Johnson ("J&J") and Johnson & Johnson Consumer Companies, Inc. ("JJCC") set forth the well-settled legal bases upon which the State's sole claim must be dismissed. The State's opposition brief is filled with a collection of irrelevant factual allegations and mischaracterizations of the law, which serve only to distract from the two straightforward legal questions that must be decided:

1. Should summary judgment be entered in favor of Defendants on the grounds that the MCPA simply does not apply to the complaint's allegations, for the reason that the MCPA defines its scope by explicitly relying upon the FTCA? The FTCA expressly states it does *not* regulate or apply to cosmetic labeling. The State now asks the Court to ignore these statutes and impose liability on Defendants based purely on a cosmetic labeling theory.

2. Alternatively, is the State's MCPA claim preempted and, therefore, subject to dismissal, in view of the fact that the FDA has squarely rejected the State's theory that talc products must carry a warning label concerning ovarian cancer?

The answer to both of these questions is *yes*. To avoid the inevitable entry of summary judgment on these two questions of law, the State goes to great lengths to avoid squarely addressing them. But the truth is that for the State's claim to survive summary judgment, the State must convince this Court to take unprecedented and extraordinary action.

First, the State asks the Court to rewrite the MCPA and dramatically expand that statute's provisions. Second, the State then asks this Court to set aside the FDA's judgment and expertise in the area of cosmetics safety—which is the FDA's exclusive jurisdiction—and overrule the FDA's findings on precisely the same alleged health risk that is the basis of the State's claims. Third, the State asks this Court to create and impose a warning label to be placed by judicial fiat on all bottles of JJCC's products, while also opening the door for judges in the 49 other states to do the same and, possibly, with different warning language. The State even refuses to say what that warning label should say (because the State admits doing so would violate federal preemption law), and so asks this Court to invent a warning label, the language of which must be judicially crafted from whole cloth. The Court should decline the State's invitations and end this case now.

I. THIS MOTION CAN BE DECIDED IMMEDIATELY

The State's opposition begins with the demonstrably false assertion that this motion is "premature" because "there are several central, genuine issues of fact" precluding the entry of summary judgment. (State Opp. Br. at 2, 5). This motion is limited to pure questions of law concerning the (1) scope of the MCPA and the (2) application of federal preemption law with regard to cosmetic labeling. Those questions of law are ripe for immediate adjudication because the State has, by a Court-ordered stipulation, dismissed all claims other than its claim that the

labeling of Defendants' cosmetic products violates the MCPA. (Opening Br. at 2). Cosmetic labeling is all that is left in this case. There is no dispute that if the MCPA by its terms does not apply to cosmetic labeling, and/or if federal preemption law prohibits the State from bringing its labeling claim, summary judgment must be entered in favor of J&J and JJCC.

None of the "issues of fact" the State lists in its opposition has even the slightest bearing on the purely legal questions raised by this motion. Similarly, it is irrelevant that discovery has not yet completed, because discovery has no bearing on the legal questions raised by J&J and JJCC's motion for summary judgment. For example, the State contends that "Defendants have not disclosed what was actually sold and when it was sold in the State of Mississippi." (State Opp. Br. at 5). Even if this were true, it has nothing to do with this motion. If J&J and JJCC are correct that the MCPA does not apply to the labeling of cosmetics, or that federal law preempts the State's claim, then it *does not matter* how many cosmetic talc products were sold in Mississippi. Put differently, every inference could be assumed in the State's favor, and the State's claim would still fail as a matter of law.[1]

The State's examples of "issues of fact" fare no better and, indeed, show why summary judgment must be granted. The State insists that the Court cannot decide this motion because it must first decide "whether the use of Talc Products causes ovarian cancer." (*Id.* at 5–6). However, it is unnecessary to decide that question if the State's claim falls outside the scope of the statute the State bases this suit upon, or if the State's claim is preempted. Moreover, as fully

[1] Additionally, this Court must disregard the purported "expert" materials filed by the State as exhibits to their opposition papers. (State Opp. Br., Exs. H, I). The instant motion raises purely legal issues, and they are for the Court to decide. As the State well knows, questions of law are *not* properly the subject of expert testimony, and it is manifestly inappropriate for the State's "expert" to purport to instruct the Court on what the law is. *See, e.g., Redhead v. Entergy Miss., Inc.*, 828 So. 2d 801, 812 (Miss. App. 2001) (noting the established rule that it is "impermissible" for a party to solicit legal conclusions from its expert).

set forth in the opening brief filed by J&J and JJCC, the FDA has already considered this issue and has affirmatively refused to require the labeling warning the State seeks here. The FDA's determination preempts the State's claim as a matter of law. The State's disagreement with the FDA's determination is irrelevant. The fact that a litigant does not share the FDA's position on a scientific issue does not and cannot affect the preemption analysis.

The State's argument appears to boil down to an incorrect assertion that even if there are questions of law that are dispositive of the action, summary judgment can *never* be granted until both fact and expert discovery are completed.[2] That is not the law in Mississippi. *See, e.g.*, *Vo v. Hancock Cty.*, 989 So.2d 414, 418–19 (Miss. App. 2008) (affirming entry of summary judgment before close of discovery where "further discovery was not warranted . . . to determine if a genuine issue of material fact existed," and where "[s]ummary judgment was adequately based on the pleadings" and other filings); *Robinson v. S. Farm Bureau Cas. Co.*, 915 So. 2d 516, 520 (Miss. App. 2005) (affirming grant of summary judgment where plaintiffs "failed to assert how the information sought was material to the legal issues and arguments presented" in defendant's summary judgment motion); *accord* Miss. R. Civ. P. 56(b) (defendant may move for summary judgment "at any time"); Miss. R. Civ. P. 1 (The Mississippi Rules of Civil Procedure "shall be construed to secure the just, speedy, and inexpensive determination of every action.").[3]

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[2] In this vein, the State highlights certain defenses by J&J and/or JJCC and insists that those "factual disputes" bar the entry of summary judgment. (State Opp. Br. at 6). But those defenses are not at issue in *this* motion. J&J and JJCC have, of course, never claimed that there are *no* disputed facts in this case. If the Court were to deny the instant motion (and it should not), the parties will have plenty of opportunity to continue discovery and delve into those factual disputes. But this case can and should be resolved on the purely legal grounds set forth in this motion, which will eliminate the need for the Court to wade into the numerous scientific and factual matters identified by the State.

[3] The State's attempt to delay a ruling on this motion is also procedurally defective. The State failed to comply with Miss. R. Civ. P. 56(f), which provides that when a party requires additional

The Court should reject the State's unsupported argument that this motion is premature, and decide now the legal questions presented.

II. THE MCPA DOES NOT REGULATE COSMETICS LABELING, AND IT CANNOT BE EXPANDED EXCEPT BY THE LEGISLATURE

This Court must decide whether the MCPA supports a labeling claim for an FDA-regulated product even though the MCPA's parent law, the FTCA, expressly disclaims it. As J&J and JJCC have explained, the MCPA does not define what constitutes an "unfair" or "deceptive" trade practice. Instead, the legislature expressly directed courts to construe the Act in accordance with Section 5(a)(1) of the FTCA, 15 U.S.C. § 45(a)(1). (Opening Br. at 5–6 (citing Miss. Code. Ann. § 75-24-3(c))). The FTCA expressly *carves out* labeling, which is not regulated by the FTC at all, but rather by the FDA.[4] (*Id.* at 6–8). This limitation—the exclusion of labeling from the scope of the statute—is built into the statutory framework of these laws, and cannot be amended except by the legislature. *See generally Wilson v. State*, 194 So.3d 855, 868 (Miss. 2016) (noting that courts have "no business amending or disregarding statutes" and "have a constitutional mandate to faithfully apply the provisions of constitutionally enacted legislation"); *Lawson v. Honeywell Int'l, Inc.*, 75 So. 3d 1024, 1027 (Miss. 2011) ("The Court must not broaden or restrict a legislative act."); *Washington v. Ga. Am. Ins. Co.*, 540 So.2d 22, 26 (Miss. 1989).

Notably, the State concedes that the FTCA "excludes questions of labeling." (State Opp. Br. at 9). And the State also concedes that, under the language of the MCPA, as well as binding

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discovery in order to oppose summary judgment, the party must set forth its reasons by affidavit. The State has submitted no such affidavit.

[4] The FTC has the experience, and under the FTCA has the statutory authority, to determine when a product claim in an *advertisement* is unsubstantiated and therefore false and misleading. But that is now immaterial to the State's claim, because the State has dismissed with prejudice its advertising claims (and any other non-labeling claims) from this action.

precedent from the Mississippi Supreme Court, this Court must look at the scope of the FTCA to determine the scope of the MCPA. (*Id.* at 8–9). Moreover, in another pending case, the State has directly conceded that claims concerning the labeling of national consumer products are properly the domain of the FDA, *not* the Mississippi Attorney General. *See State ex rel. Hood v. Johnson & Johnson*, No. 25CH1-17-cv-001528, ECF No. 12 (State's Response in Opposition to Defendants' Motion to Dismiss), at 9 ("[T]he Attorney General is not seeking to pursue a 'labeling' claim as described by Defendants, *which the State agrees would be regulated by the FDA*.") (emphasis added).

The State nevertheless argues that the Court is "not precluded from deciding what constitutes an 'unfair or deceptive trade practice' " by simply reading labeling back into the statute. (State Opp. Br. at 9). In other words, the State admits that the Court must read the FTCA's provisions to determine the scope of the MCPA—but then tells the Court to do the exact opposite of what the law says with regard to labeling.

The Court should reject the State's contorted logic. The MCPA and FTCA use clear language, and they cannot now be rewritten by the State.[5] The MCPA is clear about what matters are left to the Court's discretion. For example, section 75-24-19(1)(a) provides that if a

[5] Furthermore, the FTC, recognizing that the FTCA excludes labeling, has entered into a Memorandum of Understanding with the FDA which provides that the labeling of cosmetics products is the responsibility of the FDA rather than the FTC. (*See* Opening Br. at 6–7 (citing MOTION EXHIBIT "A," FDA/FTC Memorandum, 36 Fed. Reg. 18,539 (1971))). The courts of Mississippi are bound by the FTC's construction of the statute pursuant to the doctrine of *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *See Parkerson v. Smith*, 817 So. 2d 529 (Miss. 2002) (deferring to and following an FTC regulation and explaining that when "an agency interprets a statute that it is responsible for administering, we must defer to the agency's interpretation so long as the interpretation is reasonable.") (citing *Chevron*); *In re Mississippi Medicaid Pharmaceutical Average Wholesale Price Litigation*, 190 So. 3d 829, 841-42 (Miss. 2016); *see also Barbour v. State ex rel. Hood*, 974 So. 2d 232, 239 (Miss. 2008) (deferring to executive branch interpretation of executive branch powers, citing *Chevron*).

person has violated an injunction under the MCPA, she may be directed to pay a civil penalty in an amount to be determined by a court, up to a cap of $10,000. *See In re Mississippi Medicaid Pharmaceutical Average Wholesale Price Litigation*, 190 So. 3d 829, 847 (Miss. 2015) ("*Sandoz*") (amount of civil penalty under section 75-24-19(1)(b) left to the trial court's discretion).[6] But the Court's discretion does *not* extend to amending the MCPA to encompass whole new areas of jurisdiction—here, over product labeling—as the State now suggests.[7]

The State also contends that the Mississippi Supreme Court's recent decision in *Watson Labs, Inc. v. State*, No. 2014-CA-01213-SCT, 2018 WL 372297 (Miss. Jan. 11, 2018), allows

[6] Although it is irrelevant to the instant motion, the State nevertheless argues that *Sandoz* supports its outlandish "per-bottle" penalty theory, *i.e.*, that every unit of product sold since 1974 constitutes an individual violation of the MCPA. (State Opp. Br. at 8). The State is again wrong. The State *lost* that argument in *Sandoz*, which holds the opposite of what the State now claims. In *Sandoz*, the Mississippi Supreme Court confirmed that the "violation" for purposes of the MCPA was the defendant's allegedly false statement, and not the number of sales that resulted. *See* 190 So. 3d at 847. The Court cited the U.S. Supreme Court's decision in *United States v. Borstein*, 423 U.S. 303, 313 (1976), which held that the focus of a per-violation penalty "must be upon the specific conduct of the person from whom the Government seeks to collect the penalties." *Id.* (internal quotation marks and alterations omitted). The Court also recognized that the "number of times pharmacies were overpaid"—*i.e.*, the number of sales—"is merely a consequence of the alleged fraud, not the fraudulent conduct itself." *Id.* (quoting *State v. Abbott Laboratories*, 816 N.W.2d 145, 173–74 (Wis. 2012)). Here, too, the number of talc bottles sold is at most merely consequential and has no direct relationship to specific alleged misconduct by J&J or JJCC. Accordingly, the State cannot collect a civil penalty for each bottle of talc sold.

[7] That the MCPA excludes labeling is unsurprising, because it is not the MCPA but rather the Mississippi Product Liability Act (the "MPLA") that provides the exclusive means for recovery under Mississippi law for claims regarding a product label's omission of a warning. *See* Miss. Code Ann. § 11-1-63(a)(i)(2) (providing for liability when "[t]he product was defective because it failed to contain adequate warnings or instructions"). It is particularly notable that while the MPLA clearly covers warnings on labels in light of its express language, the MCPA, by contrast, covers "advertising, offering for sale, [and] distribution" of products—*not* labeling. *See* Miss. Code § 75-24-3(b) (" 'Trade' and 'commerce' mean the *advertising, offering for sale, or distribution* of any services and any property, tangible or intangible, real, personal or mixed, and any other article, commodity, or thing of value wherever situated, and shall include without limitation, both domestic and foreign persons, irrespective of their having qualified to do business within the state and any trade or commerce directly or indirectly affecting the people of this state.") (emphasis added); *see also Wilson v. State*, 194 So.3d 855, 868 (Miss. 2016) (noting that courts have "no business amending or disregarding statutes" and "have a constitutional mandate to faithfully apply the provisions of constitutionally enacted legislation").

this Court to ignore the FTCA. On the contrary, the Supreme Court in *Watson* affirmed the Chancellor's use of FTCA guidance to construe the MCPA. *Id.* at *13 ("Decisions of the federal courts and the Federal Trade Commission clearly 'guided' the chancellor's determination."). The issue in *Watson* was that the FTC and federal courts had applied different standards over time, and the question was whether the Chancellor had erred in applying one such federal standard rather than another. The Supreme Court answered no, because the Chancellor was not bound "to varied, changing decisions at the federal level." *Id.*

Here, J&J and JJCC are not relying on "varied, changing decisions," but rather on the straightforward statutory language of the FTCA that expressly excludes labeling from the scope of the statute. The exclusion of labeling from the FTCA existed well before the MCPA was first enacted, and has remained unchanged ever since. Again, this is not a disputed issue: the State *concedes* that labeling is outside the scope of FTCA. For the State's labeling claim to survive, the Court would have to find the exact opposite with regard to the MCPA, and completely disregard the federal statute's express and undisputed exclusion of labeling claims. That is impermissible under both *Watson* and the plain language of the MCPA itself. The Court should apply the MCPA and FTCA as written, and grant summary judgment for J&J and JJCC.

III. THE STATE'S CLAIM IS PREEMPTED BY THE FDA'S UNEQUIVOCAL REJECTION OF THE STATE'S THEORY OF LIABILITY

As fully set forth in J&J and JJCC's opening brief, the FDA has exclusive jurisdiction to regulate cosmetics labeling and to determine when warnings are required. (Opening Br. at 8–9). Indeed, the Food, Drug, and Cosmetic Act ("FDCA") expressly provides that states may not create *any* labeling requirement[8] that is "different from," "in addition to," or "otherwise not

[8] There is no question that the State's claim, which calls for an injunction to regulate the Talc Products' labels, constitutes a "requirement" for purposes of preemption. *See, e.g., Riegel v.*

identical with" what the FDA has determined is necessary. (*Id.* at 9–10 (citing 21 U.S.C. § 379s)). Thus, in order for the State to show that its claim is not preempted, it must demonstrate that its labeling theory—that the Talc Product labeling should be required to bear some type of warning alerting consumers to the supposed risk of ovarian cancer—is "identical with" the FDA's requirements. The State cannot escape preemption here, because the FDA has squarely *rejected* the State's theory. The FDA was asked, in two Citizen's Petitions, to require the exact type of warning now requested by the State, and the FDA refused, finding that the requested warnings were unsupported by the science. (*Id.* at 10–13).

The State does not meaningfully dispute that the FDA—the federal authority with exclusive jurisdiction over cosmetics labeling—has rejected the scientific basis on which the State's entire case relies. Instead, the State offers a laundry list of excuses for why this Court should ignore the FDA. None of these excuses stand up to scrutiny, and none provides a basis for denying summary judgment.

A. The State Cannot Avoid Preemption Merely by Refusing to Articulate the Warning It Seeks to Require

The State begins with a stunning admission: although its claim is premised entirely on the lack of a warning label on Defendants' products, the State argues it "has repeatedly refused to suggest [the] language" for such a warning for the Talc Products' labeling *because doing so would lead to its claims being preempted* under "the language of the FDCA." (State Opp. Br. at 11). In other words, the State contends that it can avoid preemption in this case merely by refusing to specify its claim. That, however, is nonsense.

Medtronic, Inc., 552 U.S. 312, 323–25 (2008); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521–22 (1992); *Cooper v. General Motors Corp.*, 702 So. 2d 428, 436 (Miss. 1997).

As J&J and JJCC set forth in their opening brief, the case law is clear that *any* form of judicial relief with regard to cosmetic labeling—including affirmative injunctions, negative prohibitions, and payment of money damages—would trigger federal preemption. (Opening Br. at 13–14). The State does not challenge that well-established law. In this action, the State has asked for civil penalties based on cosmetic labeling and for this Court to issue an injunction requiring the Defendants to put a warning on their labels. (Compl., Prayer for Relief ¶¶ 4, 6). Federal preemption therefore applies. Simply stated, the FDA's determination that warnings are *not* required on cosmetic talc labels is "different from" the State's claim that such warnings *are* required, and so the State's claim is preempted. *See* 21 U.S.C. § 379s.

Moreover, the State's argument is misleading. While the State refuses to set forth the "line and verse" of the warning it seeks, the State has clearly staked out its position on warnings. In the State's interrogatory responses, when asked to specify what J&J and JJCC should have warned about, the State responded that "[t]he J&J Defendants should have warned the public and specifically the citizens and residents of Mississippi not to use its Talc Products perineally or in the alternative, at a minimum, should have informed the public that perineal use of talc-containing products causes an increased risk of ovarian cancer and causes cancer in some women." *See* MOTION EXHIBIT "B," Plaintiff's Response to Defendant JJCC's First Set of Interrogatories, Doc. #248-2, at pp. 11–12. The Citizen's Petitions, which the FDA denied, requested the same thing. The 1994 Petition asked that the FDA require that talc products bear labels "with a warning such as Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer." *See* MOTION EXHIBIT "D," 1994 Citizen's Petition, Doc. #248-4, p. 2. The 2008 Petition asked the FDA to require that talc products bear labels with a warning "such as, 'Frequent application of talcum powder in the

female genital area substantially increases the risk of ovarian cancer.'" *See* MOTION EXHIBIT "E," 2008 Citizen's Petition, Doc. #248-5, p. 2. The FDA denied those requests, and that FDA action preempts the State's contrary claim. The State's attempt to conceal its position as to what the warning label should say does not affect the preemption analysis.

In addition to being inaccurate, the State's position has troubling implications. The State admits that it would violate federal preemption law if the State were to set forth the exact content of its requested warning label. And so the State asks *the Court* to violate federal preemption law, by petitioning the Court to draft an injunction requiring Defendants to warn about the alleged risk of ovarian cancer on their product labels. The Court, of course, does not share the State's luxury of refusing to consider what a judicially enforced warning label must say. *See* Miss. R. Civ. P. 65(d)(2) ("Every order granting an injunction . . . shall be specific in terms [and] shall describe in reasonable detail . . . the act or acts sought to be restrained."); *see also Illinois C. R. Co. v. George*, 130 So. 2d 260, 261 (Miss. 1961) (reversing chancellor's injunction because it "may be made more specific as to what the appellant is required to do or not to do under the injunction").

In sum, the State asks this Court to ignore the express federal preemption statute regarding cosmetic labeling, reject the FDA's denial of requests that ovarian cancer warnings be placed on talcum powder bottles, and conclude that talcum powder bottles cannot be sold in Mississippi without such a warning (and impose massive penalties on J&J and JJCC for not including a warning the FDA said did not have to be included)—and then asks the Court to write the warning that must be on the bottles. The Court should refuse. This Court should not draft cosmetic label warnings, and it certainly should not do so when the State itself is so fearful of federal preemption that it refuses to even articulate exactly what the label should say.

B. No Presumption Against Preemption Applies Here

The State's next argument is that the Court should apply a "strong presumption against preemption." (State Opp. Br. at 11–13). The State is simply wrong on the law—there is *no* presumption against preemption, much less a "strong" one, with regard to an *express* preemption clause such as the one at issue here. Under these circumstances, courts "do not invoke any presumption against pre-emption but instead 'focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.' " *Commonwealth of Puerto Rico v. Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (quoting *Chamber of Commerce of United States of America v. Whiting*, 563 U.S. 582, 594 (2011)).

Here, Congress's intent in passing the relevant preemption statute—which is entitled "Preemption for labeling or packaging of cosmetics"—could hardly be clearer. 21 U.S.C. § 379s. This Court cannot employ a "presumption" against the plain statutory language requiring preemption with regard to cosmetic labeling, and the State's attempt to argue otherwise falls flat.

C. The State's Claim Is Expressly Preempted

The State next insists that its claim is not expressly preempted pursuant to 21 U.S.C. § 379s, relying principally on an unreported decision about asbestos from a New York state trial court. (State Opp. Br. at 14 (citing *Feinberg v. Colgate-Palmolive Co.*, No. 190070/11, 2012 N.Y. Misc. LEXIS 1259 (N.Y. Sup. Ct. 2012))). The State's reliance on *Feinberg* is misplaced in several respects. First, *Feinberg* was decided *before* the FDA's determination in 2014 that warnings on talc labels were not required, and its analysis is therefore outdated. And in any event, *Feinberg* has no precedential value in New York, let alone Mississippi, and it is inconsistent with well-settled case law in both Mississippi and federal courts.

Feinberg's principal basis for declining to find preemption was that the FDA had not "issued a formal, binding regulation" that would preempt the state law. 2012 N.Y. Misc. LEXIS 1259, at *12. This reasoning ignores the principle that an affirmative federal decision *not to regulate* is entitled to equal respect and has equal force as a decision *to regulate*, as Mississippi and federal courts have recognized. *See, e.g.*, *Wansley v. Wansley*, No. 251-98-1259CIV, 2002 WL 32091072, at *10 (Hinds Cty. Cir. Ct., Miss., Aug. 28, 2002) (express preemption bars Mississippi state law claims in an area where federal authority has "considered and rejected a number of proposed suggestions" to regulate a product and "has chosen not to" do so); *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371, 375–76 (S.D.N.Y. 2014) (preemption applies where state attempts to prohibit "labeling that is *not prohibited* under federal law"). (*See also* Opening Br. at 13–16). When the FDA determines that regulatory action is unwarranted, of course it will not "issue a formal, binding regulation" saying so. *Feinberg*, 2012 N.Y. Misc. LEXIS 1259, at *12. That does not alter the fact that the FDA indisputably determined in 2014 that warnings on talc labels were unwarranted. As *Wansley*, *Bowling*, and similar cases make clear, the FDA does not have to update the Code of Federal Regulations in order to give effect to its determination that no label warning is required.

Relatedly, the State disparages the FDA's 2014 determination in response to the Citizen's Petitions and argues it carries insufficient weight for federal preemption to apply. But courts around the country routinely reject the argument that an FDA response to a Citizen's Petition cannot trigger preemption. In fact, the U.S. Court of Appeals for the Tenth Circuit has recently rejected the State's argument. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1105 (10th Cir. 2017) ("We conclude that the rejection of a citizen petition may constitute clear evidence that the FDA would have rejected a manufacturer-initiated change to a drug label."). *See also In re*

Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 930 (6th Cir. 2014); *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010).

The State specifically attacks the FDA's response to the Citizen's Petitions as not "available to the public" and "minimalist at its core." (State Opp. Br. at 15–16). The State is incorrect on both counts. First, both the 1994 and the 2008 Citizen's Petitions are publicly docketed on the federal government's regulations.gov website, both received comments from members of the public, and the FDA's response to the Petitions is available to any interested member of the public on these online dockets.[9] Second, while the State no doubt wishes the FDA's determination was "minimalist," in reality the FDA comprehensively dismantled the arguments first advanced in the Citizen's Petitions and later repeated by the State in this case.

The State also makes the strange assertion that "[t]he FDA did not refuse to add the warning" to cosmetic talc product about the supposed risk of ovarian cancer. (State Opp. Br. 15). That is *literally* what the FDA did—refuse to add warning language. *See* MOTION EXHIBIT "C" at 1 (stating that "FDA is denying your Petitions" to "require a cancer warning on cosmetic talc products"). The State further accuses the FDA of failing to address 21 C.F.R. 740.1(a). Again, the State is wrong, as the FDA response quotes the requirements of 740.1(a) verbatim. *Compare* 21 C.F.R. 740.1(a) ("The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product."), *with* MOTION EXHIBIT "C" at 1 ("Current regulations state that cosmetic products shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with a product.").

[9] For the 1994 petition's docket, see http://goo.gl/bwC2nQ; and for the 2008 petition's docket, see http://goo.gl/LnU858. (These "goo.gl" links are shortened URLs which direct the user to the respective regulations.gov pages.)

Next, the State advances the mystifying assertion that J&J and JJCC "do not and could not contend that the FDA regulates the wording of Talc labels." (State Opp. Br. at 17). This is *exactly* what J&J and JJCC contended in their opening brief. (Opening Br. at 9 (stating in bold-faced type that "The FDA Regulates Cosmetics Labeling," and explaining that this "oversight extends to talc-based cosmetics, such as the Talc Products at issue in this case")). The State then seeks to further muddy the water by introducing a new claim that the Talc Products violate the FDCA and suggesting that, as a consequence, the Mississippi Attorney General should be permitted to seek damages based on that supposed violation. (State Opp. Br. at 17). But FDCA enforcement is the province of the FDA, not the Mississippi Attorney General, and so the FDA's expressed view of talc safety is the view that must control as a matter of law.[10]

The State's attempts at misdirection should not distract from the essential inquiry: what is the impact of the FDA's 2014 determination that talc warnings are not required on the State's claim that such warnings should be required? The case law is clear—where the FDA "was given a specific invitation to regulate" in a certain area, but declined to so, that declination is "strong evidence" that the FDA did not believe the area "warrant[ed] regulation" and preempts any state claim. *E.g.*, *Bimont v. Unilever U.S. Inc.*, 14 Civ. 7749, 2015 WL 5256988, at *6 (S.D.N.Y. Sept. 9, 2015); *see also O'Connor v. Henkel Corp.*, No. 14 Civ. 5547, 2015 WL 5922183, at *11 (E.D.N.Y. Sept. 21, 2015) ("Where there is no federal requirement, there can be no state or common law liability."); *Wansley*, 2002 WL 32091072 at *10–11. Here, the FDA examined the evidence relied on by the State and concluded that a labeling change was not necessary or warranted. That determination expressly preempts the State's claim.

[10] The State's ill-advised foray into federal enforcement is also doomed by the State's own complaint, which plainly states that "[t]he Attorney General disclaims any federal remedies and *does not assert any claim for relief or seek any remedy arising out of a federal statute*." (Compl. ¶ 8). Once again, the State cannot have it both ways.

D. The State's Claim Is Also Impliedly Preempted

The State's arguments against implied preemption miss the mark as well. First, the State mounts a defense against the application of field preemption. (State Opp. Br. at 16). These arguments are irrelevant, because J&J and JJCC have never argued that the entire field has been preempted. Rather, the implied preemption argument here is tethered to the specific facts relevant to this case, in particular, the FDA's determination that talc warnings are not required.

The State's remaining arguments against implied preemption contain no references to any Mississippi case law. The State's avoidance of the *Wansley* case, which J&J and JJCC discussed at length in their opening brief, is conspicuous. (Opening Br. at 16–17 (citing *Wansley*, 2002 WL 32091072, at *10–11)). In addition to finding express preemption, the *Wansley* court held that implied preemption also barred the plaintiffs' state-law claims, reasoning that "[a]llowing such claims would open the door for 50 individual states to impose different and potentially competing requirements" on the defendant and other manufacturers. 2002 WL 32091072, at *11. The court also held that a federal determination *not* to regulate an area, after being asked to do so, has "as much preemptive force as a decision to regulate." *Id.* (quoting *Lewis v. Brunswick Corp.*, 107 F.3d 1494, 1502 (11th Cir. 1997)). *Wansley* is directly on point, and the State's failure to even attempt to distinguish it is fatal to its claim. As in *Wansley*, the Court should find the State's claims both expressly and impliedly barred, and grant summary judgment in favor of J&J and JJCC.

E. Preemption Applies to the Entire Relevant Period

The State argues that the FDCA "was not enacted until 1997," and it "may not be applied retroactively," such that "all violations of the MCPA that occurred prior to 1997 cannot be preempted." (State Opp. Br. at 19). This argument fails.

As an initial matter, the State incorrectly states that the FDCA "was not enacted until 1997." (*Id.*) The FDCA was in fact signed into law by President Franklin D. Roosevelt in 1938, and when initially enacted, as now, the statute regulated cosmetics labeling as a matter of federal law. *See* Federal Food, Drug, and Cosmetic Act, Pub. Law 75-717, 52 Stat. 1040 (1938). Only the FDCA's express preemption provision for cosmetics, 21 U.S.C. § 379s, was enacted in 1997. *See* Food and Drug Administration Modernization and Accountability Act of 1997, Pub. Law 105-115, § 412, 111 Stat. 2296, 2376.

Even so, there is no "retroactivity" issue with preemption of the State's claims here. As explained by then-Judge Sonia Sotomayor, the effect of federal preemption statutes (like the FDCA's express preemption provision) is "akin to a repeal" of the state laws within their scope. *In re St. Johnsbury Trucking Co.*, 199 B.R. 84, 87 (S.D.N.Y. 1996). Therefore, if the state law has been preempted at the time the state-law claim is litigated, the preempted state law is unenforceable irrespective of when the relevant conduct occurred. *Id. See also State v. Foley*, 950 S.W.2d 781 (Tex. App. 1997) (holding that state law was preempted even as applied to conduct that occurred prior to federal preemption statute's effective date); *In re B.C.B. Dispatch*, 201 B.R. 629 (Bankr. W.D.N.Y. 1996) (same). Express preemption therefore applies to the entirety of the State's claim, which should be dismissed in its entirety.

Moreover, the State's argument ignores the fact that its claim is both expressly and impliedly preempted. (*See* Opening Br. at 13–16 (express preemption), 16–19 (implied preemption)). Implied preemption does not rely upon the express preemption statute, and so the date of its enactment in 1997 is irrelevant to the implied preemption analysis. Thus, even if the express preemption statute did not cover the entirety of the State's claims (and it does), the State's entire claim would still fail as a matter of law as impliedly preempted.

Finally, although the Court should reject the State's retroactivity argument for the reasons stated above, it is worth noting that its argument, even accepted at face value, would not preclude summary judgment in favor of J&J and JJCC. Rather, even under the State's theory, J&J and JJCC would still be entitled to partial summary judgment on the issue of preemption with regard to all alleged violations of the MCPA from November 21, 1997 (the enactment of the express preemption provision) to the present. (*Cf.* State Opp. Br. at 19 (arguing only that "violations of the MCPA that occurred prior to 1997 cannot be preempted")).

CONCLUSION

In its opposition, the State invites this Court to commit error in several ways. First, the State asks the Court to approve an impermissible expansion of the MCPA's reach into cosmetics labeling. Amendments to the MCPA must come from the Legislature, not from the Attorney General or the courts. Because the MCPA as enacted does not reach the Defendants' alleged conduct, J&J and JJCC are entitled to summary judgment.

Second, the State asks the Court to defy the conclusions of the FDA and impose a warning on Talc Product bottles of the Court's own drafting. This Court should not reach the issue, because the FDA's prior determination defeats the State's theory and preempts the State's claim. Summary judgment should be entered in favor of J&J and JJCC.

DATED: March 15, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Meade W. Mitchell, one of the attorneys for the J&J and JJCC, do hereby certify that I have this day caused the foregoing to be electronically filed with the Clerk of the Court using the ECF system which sent notification of such filing to:

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This the 15th day of March, 2018.

/s/ Meade W. Mitchell
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Exhibit G

Valeant Defendants' Reply in Support of Motion for Summary Judgment

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, ex rel. JIM HOOD, ATTORNEY GENERAL	**PLAINTIFF**
v.	**CIVIL ACTION NO. 25CH1:14-cv-001207**
JOHNSON & JOHNSON; JOHNSON & JOHNSON CONSUMER COMPANIES, INC.; VALEANT PHARMACEUTICALS INTERNATIONAL, INC.; VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	**DEFENDANTS**

VALEANT PHARMACEUTICALS INTERNATIONAL, INC. AND VALEANT PHARMACEUTICALS NORTH AMERICA, LLC'S REPLY IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

Come Now Defendants Valeant Pharmaceuticals International, Inc.[1] and Valeant Pharmaceuticals North America, LLC (collectively "Valeant"), and join in Defendants Johnson & Johnson and Johnson & Johnson Consumer Companies, Inc.'s (collectively "Johnson & Johnson") Reply Memorandum in Further Support of Motion for Summary Judgment [Dkt. 278] (the "J&J Reply"). Rather than burden the Court with unnecessarily repetitive briefing, Valeant incorporates by reference all of the arguments set forth in the J&J Reply. Valeant also joined in the arguments and relief sought in the Motion for Summary Judgment and Memorandum in support thereof (the "Motion" and the "Joinder") submitted by Johnson & Johnson on January 26, 2018. *See* Valeant Joinder [Dkt. 258]. As more fully set forth in the Motion, Joinder, and the

[1] Valeant Pharmaceuticals International, Inc. is not involved with the manufacture, labeling, marketing, or sale of Shower to Shower®. Contrary to Plaintiff's assertion, only Valeant Pharmaceuticals International, Inc. (not Valeant Pharmaceuticals North America, LLC) disputes its role in the manufacture, labeling, marketing, or sale of Shower to Shower®. *See* Pl.'s Mem. of Law in Opp. to Mot. for Summ. J. at 6 [Dkt. 269].

J&J Reply, summary judgment should issue to Valeant for the same reasons it should issue to Johnson & Johnson.[2]

ARGUMENT

Plaintiff alleges Johnson & Johnson and Valeant violated the Mississippi Consumer Protection Act ("MCPA"), Miss. Code Ann. 75-24-5(1), by engaging in "unlawful, unfair, and deceptive business practices related to the manufacturing, sale and marketing of their talc-containing products . . . [by] failing to warn . . . that women using these products on their genital area (also known as perineal use) are at an increased risk of ovarian cancer." *See* Plaintiff's Complaint [Dkt. 002] at p. 2, ¶3.[3] It is undisputed that the talc containing products in question are cosmetic products. *See* Pl.'s Mem. of Law in Opp. to Mot. for Summ. J. (hereinafter "Pl.'s Response") at 1 n.1 [Dkt. 269].

I. Summary Judgment Is Appropriate.

Plaintiff claims that summary judgment is premature as "there are several central, genuine issues of fact" remaining. Pl.'s Response at 5. But the pending Motion for Summary Judgment puts forth only two grounds for summary judgment, the applicability of the MCPA to labeling and federal preemption—both of which are purely questions of law for which no discovery is necessary. As Johnson & Johnson notes in its Reply, it is irrelevant that discovery is not yet completed because the pending Motions for Summary Judgment only address questions of law. *See* J&J Reply at 4; s*ee also* Miss. R. Civ. P. 56(b) (defendant may move for summary

[2] Valeant reserves the right to raise additional bases for summary judgment in this action in a Motion for Summary Judgment at the close of discovery, and in the event this Motion is denied in whole or in part.

[3] Plaintiff repeatedly makes factual arguments referring to conduct of "Defendants" that date back as far as 1974. *See, e.g.*, Pl.'s Response at 1. As Plaintiff knows, Valeant did not acquire the North American rights to Shower to Shower® until September 28, 2012. Valeant has previously produced the acquisition agreements that reflect a 2012 date of execution. Accordingly, many of the factual arguments made by Plaintiff are inapplicable to Valeant prior to the date of acquisition.

judgment "at any time"). Accordingly the Court should decide the legal questions posited in the Motion for Summary Judgment now, without need for completion of additional discovery.

II. Plaintiff's Claims Fail under the MCPA.

Despite Plaintiff's claim to the contrary, the MCPA does not regulate the labeling of cosmetic products. The MCPA expressly incorporates Section 5(a)(1) of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. §45(a)(1), which is limited to issues of liability arising from advertising, and does not apply to product labeling. *See* Miss. Code Ann. §75-24-3(c). Section 75–24–3(c) provides "that in construing what constitutes unfair or deceptive trade practices that the courts will be guided by the interpretations given by the Federal Trade Commission and the federal courts to Section 5(a)(1) of the Federal Trade Commission Act (15 U.S.C § 45(a)(1)) as from time to time amended." *Watson Labs., Inc. v. State*, No. 2014-CA-01213-SCT, 2018 WL 372297, at *12 (Miss. Jan. 11, 2018). Under the FTCA, liability for allegedly false labeling is expressly omitted from the definition of an unfair or deceptive trade action. 15 U.S.C. § 52; 15 U.S.C. § 55(a)(1); *see, e.g.*, *Miles Labs., Inc. v. FTC*, 50 F. Supp.434, 437 (D.D.C. 1943) ("The dissemination of a 'false advertisement' by a corporation otherwise than on labels carried by its products is an unfair or deceptive act or practice which is declared unlawful and which the Federal Trade Commission is empowered and directed to prevent.").

As Johnson & Johnson notes in its Reply, Plaintiff attempts to mischaracterize the exclusion of labeling from the FTCA's definition as unclear and thus subject in some way to "varied, changing decisions at the federal level." *See* J&J Reply at 8–9; Pl.'s Response at 9 (quoting *Watson*, 2018 WL 372297 at *13). But contrary to Plaintiff's assertion, the FTCA **explicitly** excludes labeling from the definition of deceptive practices by statute. 15 U.S.C. § 55(a)(1) ("The term 'false advertisement' means an advertisement, *other than labeling*, which is

misleading in a material respect") (emphasis added). The guidance offered by the FTCA is clear: false labeling is not a deceptive practice under the FTCA. False labeling is excluded from the FTCA precisely because the regulation of cosmetic labeling is reserved for the FDA through the federal Food, Drug and Cosmetics Act ("FDCA"). 21 U.S.C. §393(b)(1), (b)(2)(D). Because the MCPA does not apply to labeling of cosmetic products such as those at issue in this lawsuit, Plaintiff's MCPA claims must fail and summary judgment should issue.

III. Plaintiff's Claims Are Both Expressly and Impliedly Preempted.

Plaintiff's arguments against preemption are equally unavailing. The FDCA contains an express preemption clause that prohibits state law from imposing a "requirement for labeling or packaging of a cosmetic" that is not "identical with" the FDA's labeling requirements. 21 U.S.C. §379s. Plaintiff relies in part on *Feinberg v. Colgate Palmolive Co*., 2012 WL 954271 (N.Y. Sup. Ct. 2012), an individual products liability action brought by a plaintiff alleging decades of use of talcum powder products caused her injuries. *Id.* at 1–2. While the *Feinberg* court did reject a preemption argument in that case, Plaintiff fails to acknowledge that the express preemption provision unquestionably would not have applied to such a claim because 21 U.S.C. §379a(d) excludes products liability actions from preemption. *Id.* at *5–6. However, this narrow exclusion for products liability claims does not apply to the consumer protection claims asserted by the State here.

Moreover, because the FDA alone has been charged with responsibility for regulating cosmetic labeling and has rejected a request to require the very same warning labeling here, Plaintiff's claims are also impliedly preempted. The FDA has specifically declined to require warning labeling for talc containing products warning of the risks Plaintiff seeks to have added to the label through the injunctive relief requested in this lawsuit. *See* 2014 FDA Denial of

Citizen Petition, attached as Exhibit C to Johnson & Johnson's Motion for Summary Judgment [Dkt. 248-3]. As Johnson & Johnson points out in its Reply, a government agency's decision not to regulate is equally deserving of respect as a decision to regulate. *See* J&J Reply at 13; *see also Wansley v. Wansley*, No. 251-98-1259CIV, 2002 WL 32091072, at *10 (Hinds Cty. Cir. Ct., Miss., Aug. 28, 2002). Because only the FDA may regulate the labeling and marketing of cosmetic products, the Plaintiff's claims are preempted.

Finally, Plaintiff argues that if federal preemption exists over these claims, it cannot be applied retroactively and therefore Plaintiff argues that it would only apply to claims arising after the FDCA was amended in 1997. *See* Pl.'s Response at 19. As Johnson & Johnson points out that argument fails as well. *See* J&J Reply at 17–18. However, in making its argument against retroactivity, Plaintiff expressly concedes that if preemption exists then it ***would*** apply to any alleged violations of the MCPA after 1997 when the FDCA was amended to add a preemption provision for the labeling and packaging of cosmetics. *See* Pl.'s Response at 10 and 19. As Plaintiff knows, Valeant acquired the North American rights to Shower to Shower® on September 28, 2012, well after the FDCA's preemption clause went into effect. Thus, should the Court find that FDCA's preemption exists but cannot be applied retroactively, Valeant is still entitled to summary judgment as the only alleged violations by Valeant occurred, or could have occurred, after the September 28, 2012 acquisition.

CONCLUSION

For the same reasons set forth in the Motion for Summary Judgment [Dkt. 248] and Johnson & Johnson's Reply Memorandum in Further Support of Motion for Summary Judgment [Dkt. 278], Valeant hereby respectfully requests the Court to enter summary judgment and

dismiss all claims against Valeant with prejudice. Valeant further requests any such further and additional relief as the Court deems appropriate.

THIS, the 15th day of March, 2018.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Elizabeth R. Hadley, hereby certify that on this day I have electronically filed the foregoing with the Clerk of the Court using the MEC system which sent notification of such filing to the following counsel of record:

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This the 15th day of March, 2018.

/s/ Elizabeth Ross Hadley
ELIZABETH R. HADLEY

Exhibit H

Agreed Order and Stipulation Dismissing Certain Claims

IN THE CHANCERY COURT OF THE FIRST JUDICIAL DISTRICT
OF HINDS COUNTY, MISSISSIPPI

THE STATE OF MISSISSIPPI, Ex rel.
JIM HOOD, ATTORNEY GENERAL

PLAINTIFF

V.

CIVIL ACTION NO. 25CH1:14-cv-001207

JOHNSON & JOHNSON, JOHNSON &
JOHNSON CONSUMER COMPANIES, INC.,
VALEANT PHARMACEUTICALS
INTERNATIONAL, INC.; and VALEANT
PHARMACEUTICALS NORTH AMERICA, LLC

DEFENDANTS

AGREED ORDER AND STIPULATION DISMISSING CERTAIN CLAIMS

This matter is before the Court pursuant to Miss. R. Civ. P. 41(a) and the *ore tenus* motion of Plaintiff, the State of Mississippi *ex rel.* Jim Hood ("the State"), and Defendants, Johnson & Johnson ("J&J"), Johnson & Johnson Consumer Companies, Inc. ("JJCC"), Valeant Pharmaceuticals International, Inc. ("VPII"), and Valeant Pharmaceuticals North America, LLC ("VPNA"), to dismiss certain claims asserted by the Plaintiff in this matter.

In the Complaint, Plaintiff asserts violations of the Mississippi Consumer Protection Act, Miss. Code Ann. §§ 75-24-1, *et seq.* (the "MCPA") with regard to Johnson's Baby Powder and Shower to Shower ("the Talc Products"). Plaintiff now agrees, and the parties stipulate, that Plaintiff will not pursue injunctive and/or monetary relief, including civil penalties, fines and/or damages under the MCPA premised in any way upon any advertisement that does not appear on a product label and/or packaging — including, but not limited to, print, television, radio, social media and Internet advertisements—or any other claimed misrepresentation or omission that is not part of a product label and/or packaging.

This agreed order and stipulation does not, and is not intended to, prejudice or dismiss the remaining claims asserted in the Complaint. It specifically preserves all claims wherein Plaintiff seeks damages based on a per-container (bottle) unit analysis for disgorgement and civil penalties arising from alleged misleading statements made on product labeling and/or packaging in the State of Mississippi.

This agreed stipulation and order does not, and is not intended to, affect future determinations of relevance or admissibility of advertisements concerning the Talc Products for other purposes, such as Plaintiff's proof of liability; Plaintiff's offer of (and any objection to) said material is subject to the applicable rules of evidence. This agreed order and stipulation does not prejudice the Defendants from asserting any available defenses, including challenges to damage models advanced by Plaintiff.

After review, and upon noting the agreement of the parties, the Court finds that this request is well taken and should be granted. As such, the Court approves this agreed order and stipulation dismissing certain claims as described herein.

THEREFORE, IT IS ORDERED AND ADJUDGED that Plaintiff's claims alleged in the Complaint for civil penalties, fines and damages for violation of the Mississippi Consumer Protection Act, Miss. Code Ann., §§ 75-24-1, *et seq.*, that are premised on Defendants' advertising, marketing, or promotion of the Talc Products that is not part of a product label and/or packaging; any misrepresentation or omission regarding the Talc Products that is not part of a product label and/or packaging; and otherwise described in this order, are hereby dismissed with prejudice. All other claims of Plaintiff asserted in this matter are preserved, including Plaintiff's claims based on a per-container (bottle) unit analysis for disgorgement or product labeling and/or packaging for the Talc Products sold in the State of Mississippi. This dismissal does not impact any defense available to Defendants on the remaining claims.

SO ORDERED, this the 13th day of October, 2017.

CHANCERY COURT JUDGE

AGREED TO BY:

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State of Mississippi, ex rel.
Jim Hood, Attorney General

Counsel for Defendants
Johnson & Johnson
Johnson & Johnson Consumer Companies, Inc.

Counsel for Defendants
Valeant Pharmaceuticals International, Inc.
Valeant Pharmaceuticals North America, LLC

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